

**Instructions:**

- Do not change the order of the headings unless required by local regulations. ICF Author is responsible for ensuring that all the required IC elements are included as per the applicable regulation(s).

**To finalize the Country Template:**

- Delete version name and date in header.
- <<Insert XXX here>> - Country-specific template information to be added. Remove purple highlighting to finalize Country Template.
- Red italic text – Instructions for ICF author to create the Country Template. Remove to finalize Country Template.
- Remove the above instructions to finalize Country Template.

**To finalize the Study-specific Country ICF to be submitted to IRB/EC:**

- Green italic text – Instructions for ICF Author to create the Study-specific Country ICF. Remove before IRB/EC submission.
- Insert language from the Study Specific Language Tool “SSL” where indicated.
- Black text: can be modified as needed as long as it does not contradict the protocol / study information and retains the necessary elements as per applicable regulations.
- Grey Highlighted Text: Must remain unchanged unless approval from the correct function is received. Grey highlighting to be removed before IRB/EC submission.
- <<Insert XXX here>> –Add Study-specific and site-specific information and remove yellow highlighting before IRB/EC submission.
- \* = Legal language. All modifications must be approved by Legal. Delete “\*” before IRB/EC submission.
- Remove the above instructions before IRB/EC submission.

## Research Study Participant Information Sheet and Consent Form

<i>Add, delete and/or modify contact details per country requirements.</i>	
<b>Main Study Title:</b>	<<title (must match protocol)>>
<b>Protocol Number:</b>	<<Protocol number>>
<b>Sponsor:</b>	AbbVie Healthcare India Private Limited
<b>CONTACT INFORMATION:</b>	
<b>Study Doctor:</b>	<<Insert investigator's name>>
<b>Address:</b>	<<Insert clinic and hospital>>
<b>Telephone:</b>	<<Insert site's contact numbers>>
<b>After Hours Telephone:</b>	<<Insert site's after hours contact numbers, if applicable>>
<b>Ethics Committee or other contact information, if applicable</b>	<< Insert Contact details>>

### INTRODUCTION

You are being asked whether you would like to voluntarily participate in a research study of an investigational product(s) called <<insert name of study drug and/or device>> which may be referred to in this document as “study product(s),” “study drug,” or “study device.”

#### What is a research study?

A research study is an experiment whose purpose is to answer specific questions, such as:

- Does this study product work? Is it safe?
- What kind of treatment is better?

We refer to it as the “study” in this document. This study is approved by <<insert local Competent Authority if applicable>> and the Ethics Committee.

The name of the sponsor for this study is listed in the table above and is referred to as “AbbVie” or “sponsor” in this document. AbbVie pays <<insert Institution name>> to run the study.

Being in this study does not replace your medical care.

Feel free to talk about this study with your family, friends, study doctor and personal doctor before you decide. We will answer any questions you may have so that you can make an informed decision.

When reading this document, please note that the words "you" and "your" refer to the person in the study and not a parent, guardian or legally authorized representative who may sign this document on behalf of the person in the study.

<<INSERT STUDY SPECIFIC LANGUAGE FROM TOOL>>

### <<PURPOSE/BACKGROUND OF STUDY>>

<<Include an explanation of the purpose of the study. The ICF must also include the expected duration of the study and the approximate number of participants.>>

The approximate number of participants in this research study are [•].

The expected duration of the study is [•].

### <<PROCEDURES >>

<<The ICF must include, without limitation, the following information:

- Description of the procedures to be followed, including all invasive procedures;
- Details of the trial treatment schedule;
- For randomized trials, the probability for random assignment to each treatment;
- Statement that there is a possibility of failure of investigational product to provide intended therapeutic effect;
- For placebo-controlled trials, a statement that the placebo will not have any therapeutic effect>>

### **Trial Treatment Schedule**

<<Include details of the trial treatment schedule>>

\*<<Include the following language right after SSL (study specific language) describing the procedure(s)/activity(ies) of taking identifiable image/photo/video/voice recordings and complete the yellow highlighted portions as appropriate. This language is required ONLY if images/photos/video/voice recordings that MAY IDENTIFY study participant may be provided to AbbVie as part of the study. This description is for Identifiable Recordings that are mandatory for participation in the main study since this is the main study ICF template. (If

*Identifiable Recordings are optional, they should be described in the separate optional research ICF.) If not applicable, please delete>>*

You may be identified from **<<select as appropriate images/photos/videos/voice recordings>>** that are taken as part of the study. The **<<select as appropriate images/photos/videos/voice recordings>>** are referred to in this document as “**Identifiable Recordings**.” Your Identifiable Recordings will be provided to AbbVie, its affiliates, its service providers, and its research partners and retained by AbbVie, its affiliates, its service providers, and its research partners as part of the study data submitted by the study doctor. If you do not want to have the Identifiable Recordings provided to and retained by AbbVie, its affiliates, its service providers, and its research partners, you cannot take part in the study. Please refer to the section entitled, “Information About Confidentiality and Data Protection,” for more details on how the Identifiable Recordings will be used and protected. In addition, in the “Use of Identifiable Recordings in Scientific, Educational and Promotional Materials” section, you can find information about what to do if you no longer want AbbVie to use your Identifiable Recordings.

### **\*USE OF BIOLOGICAL SAMPLES**

*<<If it is possible that subject samples will be used by anyone other than AbbVie or people or companies that AbbVie works with, consult Legal. Note that the procedures section of the ICF will still have to describe what type of samples will be collected (e.g., blood, tissue), how (e.g., blood draw, biopsy), any long-term storage period, and for what purpose. Note that the Use of Biological Samples section already includes the storage period and purpose of the biomarker samples. The “Use of Biological Samples” section addresses the commonalities among samples, including who will test them, storage period, and use of a unique code.>>*

The biological samples (such as blood, urine, stool, and tissue) that we collect from you will be stored, processed and used as described in this document. Collection of some of these samples may be optional. Please refer to the separate “Research Study Participant Information Sheet and Consent Form to Participate in Optional Research” to see which samples are optional.

Biological samples collected during the study will be tested by the study site, central laboratory, AbbVie, and/or companies or people working with AbbVie. Unless otherwise specified, samples will be destroyed once all required tests and analyses are completed.

AbbVie will not sell your biological samples to other people or companies. All biological samples collected from you will be given a unique code to protect the confidentiality of your Personal Data. Please refer to the section entitled, “Information About Confidentiality and Data Protection,” for more details. In addition, in the “Voluntary Participation and Withdrawal” section, you can find information about what to do if you no longer want AbbVie to use your biological samples.

*<<\*\*\*Include biomarker research wording if applicable to the main study. Otherwise, remove it. **Select ONLY ONE of the following options.***

### **Biomarker Research: Purpose, Sample Use and Storage**

***Biomarkers research Option 1: If the study is NOT an aesthetics study, select this option 1 and delete option 2.>>***

>> Samples collected for biomarker research may be retained and studied for up to 20 years from the end of the study and then destroyed. Biomarker research can help us better understand:

- How to diagnose, monitor, and treat <<insert the disease or condition being studied>> (and related conditions);
- Why and how some patients with <<insert the disease or condition being studied>> respond to the study product(s) or products of the same or similar class; and/or
- How the study product(s) being studied may affect and/or interact with your body.

Your biological samples collected for biomarker research may be studied for genetic material (instructions for cells to work that is in the form of DNA and RNA), proteins or parts of proteins (a part of all cells), and/or other molecules of cell metabolism (such as sugars and fats). All of this research is an effort to develop new therapies, diagnostic tests, research methods, and/or technologies.

Your biological samples collected for biomarker research will only be used by AbbVie (and/or people or companies working with AbbVie) for the purposes described in this document. AbbVie will not sell your samples to other people or companies, nor will AbbVie use them for future, unspecified research.

Biomarker research is exploratory in nature and cannot help your doctor or the study doctor treat your disease or condition. For this reason, you will not get the results of any testing that is done as part of biomarker research.>>

***Biomarkers research Option 2: If the study is an AESTHETICS study, select this Option 2 (which is biomarkers research language specific to aesthetics studies) and delete option 1.***

<<Samples collected for biomarker research may be retained and studied for up to 20 years from the end of the main study and then destroyed. Biomarker research can help us better understand:

- How to treat skin related aesthetic conditions (and related conditions);
- Why and how patients respond to skin related aesthetic devices or similar devices; and/or
- How skin related aesthetic devices may affect and/or interact with your body.

Your biological samples collected for biomarker research may be studied for genetic material (instructions for cells to work that is in the form of DNA and RNA), proteins or parts of proteins (a part of all cells), and/or other molecules of cell metabolism (such as sugars and fats). All of this research is an effort to develop new therapies, diagnostic tests, research methods, and/or technologies.

Your biological samples collected for biomarker research will only be used by AbbVie (and/or people or companies working with AbbVie) for the purposes described in this document. AbbVie will not sell your samples to other people or companies, nor will AbbVie use them for future, unspecified research.

Biomarker research is exploratory in nature and cannot help your doctor or the study doctor treat your disease or condition. For this reason, you will not get the results of any testing that is done as part of biomarker research.>>

## RISKS

<<Include reasonably foreseeable risks or discomforts to the study participant. If applicable also include a statement if a particular treatment or procedure may involve risks to the study participant (or to the embryo or foetus, if the study participant is or may become pregnant), which are currently unforeseeable.>>

The following are some reasonably foreseeable risks or discomforts that you may experience:

[•]

## BENEFITS

<<Include a description of any benefits to the study participant or others reasonably expected from the research. If no benefit is expected, the ICF should make this clear so that the potential participant can be made aware.>>

[•]

## RESPONSIBILITIES OF THE SUBJECT

<<Include any responsibilities of the study participant with which they are required to comply>>

[•]

## ALTERNATIVE PROCEDURES OR THERAPIES

<<Include an explanation of specific, appropriate alternative procedures or therapies available to the study participant>>

[•]

## NEW INFORMATION

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

## \*COSTS

You will not have to pay for the study product(s) or for any tests, procedures or medications that are required by the study.

## \*REIMBURSEMENT AND PAYMENTS

You may be reimbursed for your actual travel expenses incurred to attend completed study visits.

You will not be paid to participate in the study or for the use of your biological samples <<add if identifiable recordings are provided to AbbVie as part of the study: or Identifiable Recordings>>. AbbVie and people or companies working with AbbVie may use your

biological samples when developing new tests, procedures and commercial products. If this happens, AbbVie does not plan to share any profits with you.

#### **\*RESEARCH RELATED INJURIES**

In case of an injury occurring to you during the study, free medical management shall be given to you as long as required or until such time it is established that the injury is not related to the study, whichever is earlier.

In the event of a study-related injury or death, AbbVie, the study doctor, or study site, as the case may be, in accordance with the Rule 39 of the New Drugs and Clinical Trial Rules, 2019, as the case may be, shall provide financial compensation for the injury or death.

You will not lose any of your legal rights or release AbbVie, the study doctor, or the staff from liability for mistakes or intentional misconduct by signing this document.

If you are injured during this study, your study doctor will discuss with you the available medical treatment options.

#### **\*INFORMATION ABOUT CONFIDENTIALITY AND DATA PROTECTION**

This confidentiality section describes your rights and explains how personal information about you including information derived from your biological samples and other information about your health, as well as any images, photos, video, or voice recordings collected during the study, will be used, shared and protected. This type of information is referred to as “**Personal Data**” and it is protected by data protection law. AbbVie and the study doctor and staff working on this study must comply with applicable data protection law. Before Personal Data is shared with AbbVie, the study doctor and staff will replace any information that could directly identify you (such as your name, address, and contact information) with a generic code which AbbVie cannot link to your identity. In addition, any features that can identify you on images, photos, video or voice recordings taken of you as part of your participation in the study will be blocked/masked when maintained by AbbVie. Such Personal Data without directly identifying information is referred to as “**Coded Data.**” *<<Add the following language ONLY if, per protocol requirements, AbbVie may be provided with images/photos/video/voice or audio recordings that COULD IDENTIFY the research subjects. Otherwise – please delete.* For this study we are also collecting Identifiable Recordings described earlier in this document, which may directly identify you and which will be shared with AbbVie, as well as affiliates, service providers and research partners of AbbVie. Unless we specifically state a different or additional purpose, the Identifiable Recordings will be used and shared for the same purposes as Coded Data described in this document.>>

#### **Who is the data fiduciary of my Personal Data?**

The sponsor, AbbVie, is the data fiduciary of the Personal Data collected or created for purposes of the study because the sponsor is responsible for deciding what Personal Data will be collected for the study and how it will be used. This includes the Coded Data *<<Add ONLY if images/photos/video or voice recordings that could identify the subjects will be provided to AbbVie. Otherwise delete.* and Identifiable Recordings>> shared with AbbVie, as well as Personal Data contained in the study documents maintained at the study site. The study site

and study doctor will continue to be the data fiduciaries of Personal Data contained in your medical records because they are responsible for deciding how your Personal Data will be used for your medical care that is unrelated to the study.

As described earlier in this document, AbbVie will only receive Coded Data and will not be able to directly identify you <<Add ONLY if images/photos/video or voice recordings that could identify the subjects will be provided to AbbVie. Otherwise delete. with the exception of the Identifiable Recordings as described in this document>>. Further, AbbVie will only access Personal Data controlled by the study site for the limited purposes explained in the “How will my Personal Data and biological samples be protected?” section below.

We are asking you to consent to the collection, use and sharing of your Personal Data with others as explained in this section. If you don't consent, you will not be able to participate in the study.

### **What Personal Data about me will be collected?**

To help answer the research questions, the study doctor and staff will collect certain Personal Data about you from your existing medical records so they can understand your medical history. In addition, they may collect your Personal Data from available public records. Also, during the study, they will collect information self-reported by you as well as their observations of you.

The following are examples of Personal Data that may be collected:

- your name, address, telephone number, date of birth, gender/sex, race/ethnicity, medical record numbers and/or other identifying information
- your qualification, occupation, annual income, and nominee's name, address, and relationship to you
- results of examinations and laboratory tests including blood tests, medical imaging, genetic tests, tissue sample tests or other medical procedures
- information regarding your health and medical history, including information derived from your biological samples (for example, blood, urine, and tissue), health conditions, treatments, medical procedures, and survival status, including related dates;
- your images, photos, video, and voice recordings.

### **How will my Personal Data be used?**

Listed below are examples of how your Personal Data <<Add ONLY if images/photos/video or voice recordings that could identify the subjects will be provided to AbbVie. Otherwise delete. (including your Identifiable Recordings)>> may be used for the purposes of this study:

- to determine if you can participate in this study;
- to evaluate how your health or condition changes during the study and compare it to other study participants;

- to find out if treatment with the study product(s) is safe and effective and to follow up with you if needed for safety reasons after the study is completed;
- to learn more about the disease(s) or condition(s) that are the subject of the study;
- to report safety data, such as adverse reactions or events, product complaints, or pregnancies, related to a medical product and/or device used in this study to its manufacturer;
- to provide you with reimbursement of your travel expenses << add only if your country allows payments other than reimbursement of actual travel expenses, otherwise delete and/or compensation for your time and inconvenience>> for attending study visits; and
- to provide you with treatment and reimbursement of medical expenses and financial compensation in the event of a study-related illness, injury, or death.

AbbVie may use your Personal Data including your Coded Data <<Add **ONLY if images/photos/videos or voice recordings that could identify the subjects will be provided to AbbVie. Otherwise delete** and your Identifiable Recordings>> based on your consent, AbbVie's legitimate interests in the scientific research described in this document, or to comply with a legal obligation.

Your Coded Data<<Add **ONLY if images/photos/video or voice recordings that could identify the subjects will be provided to AbbVie. Otherwise delete.** and your Identifiable Recordings,>> collected for this study may also be used for compatible purposes in continued medical research projects or scientific research purposes. Such continued analysis will focus on the study product(s), treatment, disease or condition (or similar disease or condition) that are the subject of this study and could include:

- further examination of the safety or efficacy of any medical product or treatment included in the study;
- identification of new medical uses of any medical product or treatment included in the study;
- further examination of the disease(s) or condition(s) that are the subject of the study or similar diseases or conditions; and
- analysis of how AbbVie can improve its clinical research processes.

### **Who will receive my Personal Data and biological samples?**

The study doctor and staff will share your Coded Data and biological samples with AbbVie and its representatives for the purposes described above. The study doctor and staff and AbbVie may share your Coded Data and biological samples with AbbVie's affiliates, as well as with AbbVie's service providers and research partners in countries around the world. The study doctor and staff may also share your Personal Data and Coded Data with their service providers helping conduct the study.

The study doctor and staff may also share your Personal Data and AbbVie may share your Coded Data with regulatory authorities in countries around the world and with the ethics committees responsible for oversight of this study. These bodies are responsible for ensuring that the research is being conducted properly, in accordance with laws and ethical

requirements, and they may use your Personal Data in order to fulfil their duties. Regulatory authorities may also use your Personal Data to evaluate and confirm the validity of the study findings.

AbbVie may share Coded Data contained in safety data with the manufacturer of the medical product and/or device used in this study.

You have the right to request a list of the recipients with whom your Personal Data is shared, along with the description of the Personal Data so shared. For more information about exercising your data protection rights, please see the “Can I see my study records; what rights do I have?” section.

The results of this study, including Coded Data, may be published in study reports or scientific presentations and publications. They may also be used in educational, promotional, marketing, and commercial materials distributed publicly worldwide relating to the study product(s) or disease(s) or condition(s) that are the subject of the study. **Information or features that identify you or that reasonably could be used to identify you will be removed to protect your identity.**

*Add if IDENTIFIABLE images/photos/videos or voice recordings are provided to AbbVie as part of this study. Otherwise delete.*

## **USE OF IDENTIFIABLE RECORDINGS IN SCIENTIFIC, EDUCATIONAL AND PROMOTIONAL MATERIALS**

### **Scientific Materials**

If Identifiable Recordings were taken as part of your participation in the main study, they will be included in your study records and may be used in study reports, scientific presentations and publications. To ensure the scientific integrity of the study, Identifiable Recordings cannot be deleted from study records or reports but you can ask us to stop using them in scientific presentations and publications. If you do so, Identifiable Recordings will not be used for any scientific presentations and publications created after the date of your request, but we will not be able to remove or change the way Identifiable Recordings were used before the date of your request.

### **Promotional and Educational Materials**

AbbVie will initially own the copyright of your Identifiable Recordings and will have the right to transfer, assign, or license the copyright of the Identifiable Recordings, as needed. If you opt-in by checking the box at the end of this document, you are granting AbbVie the right to use, permit others to use or transfer the rights to your Identifiable Recordings for purposes of including them in educational materials, training seminars, and promotional, marketing, and commercial materials distributed publicly worldwide relating to the study product(s) or disease(s) or condition(s) that are the subject of the study. Before you decide whether to opt-in, please note:

- (1) Opting-in to such use is **OPTIONAL**. You do not need to opt-in to these uses in order to participate in the study. At the end of this document, we ask for your consent.
- (2) AbbVie may make Identifiable Recordings which include your Personal Data (including sensitive data) public.
- (3) You can ask us to stop using Identifiable Recordings at any time.
- (4) If you ask us to stop, Identifiable Recordings will not be used for any educational, promotional, marketing, and commercial materials created after the date of your request, but we will not be able to remove or change the way Identifiable Recordings were used before the date of your request.

### ***How will my Personal Data and biological samples be protected?***

The study doctor and staff will store your Personal Data in a limited-access, secure storage space. They are required by law to protect the confidentiality of your Personal Data and to use and disclose it only as described in this document. Representatives of AbbVie, regulatory authorities, and the ethics committee overseeing this study may be provided with access to Personal Data controlled by the study site to verify that the study data is being reported accurately and that the study is being conducted properly. The study doctor will retain your Personal Data for as long as required by local laws and regulations or for a longer period if required by an agreement with AbbVie.

AbbVie will store the Coded Data and biological samples that it receives in a limited-access, secure storage space. AbbVie has implemented security measures to prevent unauthorized individuals from accessing your Coded Data and biological samples. AbbVie will only use your Coded Data and biological samples for the purposes described in this document. Before sharing your Coded Data, AbbVie will require each of its affiliates, service providers and research partners to sign a written agreement requiring them to protect your Coded Data and use it only for the purposes described in this document. AbbVie may also employ anonymization and de-identification techniques to further reduce the ability to identify individuals from Coded Data. AbbVie may retain the Coded Data reported to it for as long as the study product(s) is used or longer if required by local laws and regulations, consistent with Good Clinical Practices (GCP) and clinical trial related laws and regulations.

Some of AbbVie's affiliates, service providers and research partners may be located outside your home country where data protection laws may offer less protection than in your home country. Any Coded Data that is transferred to AbbVie's parent company, AbbVie Inc., in the United States, or other AbbVie affiliates is done under internal privacy agreements. Any transfers of Coded Data to AbbVie's service providers or research partners outside your home country will be done in compliance with applicable law and the international data transfer restrictions that apply.

### ***\* Can I see my study records; what rights do I have?***

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.

You may have the right to see and get a copy of your study records, or to request correction if you believe your Personal Data is not accurate or complete. Please note that your access to your study records may be suspended during your participation in the study. If you want to immediately access your study records, you may not be able to continue participating in the study.

In addition, you have the right to request information on how the Coded Data reported to AbbVie and your Personal Data collected by the study doctor and staff is being used and shared, including that you have the right to request a list of the recipients with whom your Personal Data is shared. You can also request the deletion or restriction of use of any Personal Data that are not required to comply with regulatory requirements and are no longer needed. Please be aware that because AbbVie only maintains Coded Data, AbbVie may not be able to fully respond to your request. You should direct your request about Coded Data that AbbVie maintains to the study site and ask the study site to forward your request to AbbVie. If AbbVie cannot meet your request, it will provide the reason.

You may nominate any other individual to exercise your rights in the event of your death or incapacity, in accordance with the provisions of applicable law.

You also have a right to take back your permission to collect, use and share your Personal Data. Please refer to the "Voluntary Participation and Withdrawal" section below for more details.

Please note that you are entitled to lodge a complaint with your local data protection authority if you have concerns with how AbbVie or the study doctor or staff are using your Personal Data.

In the "Contact Information" section below, you can find information about who to contact if you want to request a copy of your study records, have access to them to correct your Personal Data, or to request information or have questions or concerns regarding how your Personal Data is being used and shared.

#### **\*Grievance Redressal Mechanism**

In the event of any concerns or grievances related to any act or omission of the sponsor, AbbVie, in processing your Personal Data, you are encouraged to reach out to the grievance redressal officer by submitting a detailed description of the grievance at [abbvie.com/privacy-inquiry.html](http://abbvie.com/privacy-inquiry.html) or by sending an e-mail to [privacyoffice@abbvie.com](mailto:privacyoffice@abbvie.com).

All grievances will be treated with confidentiality, and efforts will be made to resolve them promptly and fairly.

#### **\*VOLUNTARY PARTICIPATION AND WITHDRAWAL**

##### ***Do I have to participate?***

Participation in the study is voluntary. The study may be stopped early by AbbVie, the study doctor, the ethics committee or organizations that regulate research in India or other countries. You could be withdrawn from the study without your consent, at any time and for any reason, including without limitation:

- If the study appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

### ***Can I change my mind?***

If you start the study, you may stop at any time without further explanation. You may also request that we stop collecting and sharing your Personal Data, but you will not be able to continue in the study.

If you want to take back your permission to use or disclose your Personal Data, or biological samples or if you want to stop participating in the study for any reason you must let the study doctor know in writing. You will not be punished or lose any benefits to which you are otherwise entitled.

*\*<<Include a description of the procedures for orderly termination of participation by the participant in case they withdraw or are withdrawn from the study.>>*

### ***What will happen to my biological samples and Personal Data?***

#### **Biological Samples**

If you withdraw or are withdrawn from the study, the biological samples we have collected from you as part of the study will continue to be stored and analyzed as described in this document unless you specifically withdraw your permission. If you withdraw your permission to use your biological samples, no new research work will be started, and your biological samples will be destroyed unless a regulatory authority requires AbbVie to keep them. If AbbVie and/or other researchers did any testing of your biological samples before you withdrew your permission, AbbVie will still use and disclose the test results and keep the data generated from your biological samples due to regulatory requirements that are designed to safeguard scientific integrity.

#### **Personal Data**

If you withdraw or are withdrawn from the study, the study doctor or staff may continue to follow up with you regarding your health status. If you are withdrawn because you become pregnant, the study doctor and staff will also collect information about your pregnancy.

This information will include:

- Your date of last menstrual period
- General information about your past pregnancies which may include:
  - Number of pregnancies and their outcome
  - Number of elective or spontaneous abortions
- Information about your current pregnancy which may include:

- Forms of birth control used
- Estimated and actual date of delivery
- Complications during pregnancy, labor or delivery
- After the baby is born:
  - Your baby's birth weight and length
  - Your baby's gender
  - Information about any birth defects that your baby has and any tests or procedures that were performed to diagnose them.

You can always withdraw your permission for the collection of your Personal Data or withdraw your permission to participate in the follow up. You should inform your study doctor about this when you withdraw or are withdrawn from the study.

Even if you withdraw your permission to participate in follow up, or you withdraw your permission for the collection of your Personal Data, we may still collect a limited amount of new Personal Data: (i) information about your survival status from available public records, and (ii) safety information that may be related to your participation in the study. We need to continue to collect this type of information because of legal and regulatory requirements and AbbVie's legitimate interests in the scientific research described in this document.

Personal Data that has already been collected prior to your withdrawal cannot be deleted from study records to ensure the scientific integrity of the study.

Even after your withdrawal, the study doctor and staff and AbbVie may be required to include your information in analyses and aggregate study results, but in a way that will not identify you << Add ONLY if IDENTIFIABLE images/photos/videos or voice recordings will be provided to AbbVie. Otherwise delete: with the exception of the Identifiable Recordings obtained as part of the study>>.

## CONTACT INFORMATION

If you have any questions, problems or concerns you should contact the study doctor or the Ethics Committee at the phone numbers listed on Page 1 of this Consent to Participate in a Research Study. The Ethics Committee can also provide more information regarding your rights as a research subject.

To request a copy of your study records, to make a request to exercise your rights of access, deletion, objection, transfer, restriction, correction, or withdrawal, to request information on how the Coded Data reported to AbbVie or the Personal Data maintained by the study site is being used and shared, or to raise questions, concerns, or complaints as to how AbbVie is using your Coded Data, you may contact **Contact Person at Study Site** at **Contact Information**. In addition, you are entitled to lodge a complaint with your local data protection authority.

You can submit your personal data inquiries to AbbVie at [abbvie.com/privacy-inquiry.html](http://abbvie.com/privacy-inquiry.html) or by sending an e-mail to [privacyoffice@abbvie.com](mailto:privacyoffice@abbvie.com).

If you are harmed by the research or have any questions or concerns about the study product(s) you should contact the study doctor immediately for further instructions.



**\*PRIVACY CONSENT**

By signing the Informed Consent Form, below:

- I consent to the collection, use and sharing of my Personal Data as described in this document.
- *<<Add ONLY if collection and sharing with AbbVie of identifiable images/photos/video or voice recordings is MANDATORY for study participation. Otherwise delete:* I consent to the collection, use, and sharing of my Identifiable Recordings as described earlier in this document.

*<<Add ONLY if collection and sharing with AbbVie of identifiable images/photos/video or voice recordings is MANDATORY for study participation. Otherwise delete:*

**Use of Identifiable Recordings in Promotional Materials and Educational Materials:**

- Yes, AbbVie has my additional consent to use, transfer, assign, and license the Identifiable Recordings of me, without further compensation, and without my review or further approval, for the educational, training, and promotional purposes described earlier in this document.

*Include the checkbox below for studies that allow subjects to receive study text message reminders, otherwise please delete.*

**Text Message Reminders**

- I consent to receive recurring text messages from AbbVie and companies working on AbbVie's behalf, including study related reminders, to the number indicated below. Message and data rates apply. My consent is not a condition for study participation or to receive other goods and services. I can text STOP to opt-out at any time. Mobile/Cell Phone Number (Including Area Code): \_\_\_\_\_

## Informed Consent form to participate in a clinical trial.

Study Title:

Study Number:

Subject's Initials: \_\_\_\_\_

Subject's Name: \_\_\_\_\_

Date of Birth / Age: \_\_\_\_\_

[Address of the Subject \_\_\_\_\_]

Qualification \_\_\_\_\_

Occupation: Student/Self-Employed/ Service/Housewife/Others (Please tick as appropriate)

Annual Income of the subject \_\_\_\_\_

Name and address of the nominee(s) and his relation to the subject \_\_\_\_\_ (for the purpose of compensation in case of trial related death).]

Please  
initial box  
(Subject)

- (i) I confirm that I have read and understood the information sheet dated \_\_\_\_\_ [ ]  
for the above study and have had the opportunity to ask questions and my questions have  
been answered to my satisfaction.
- (ii) I understand that my participation in the study is voluntary and that I am \_\_\_\_\_ [ ]  
free to withdraw at any time, without giving any reason, without my medical  
care or legal rights being affected.
- (iii) I understand that the Sponsor of the clinical trial, others working on the \_\_\_\_\_ [ ]  
Sponsor's behalf, the Ethics Committee and the regulatory authorities will not  
need my permission to look at my health records that directly identify me both  
in respect of the current study and any further research that may be conducted  
in relation to it, even if I withdraw from the trial. I agree to this access. However,  
I understand that my identity (name and contact information) will not be  
revealed in any information released to third parties not described in the  
information sheet or published.
- (iv) I agree not to restrict the use of any data or results that arise from this \_\_\_\_\_ [ ]  
study provided such a use is consistent with the descriptions of use in the participant  
information sheet.
- (v) I agree to take part in the above study. \_\_\_\_\_ [ ]
- (vi) I am not giving up any of my legal rights by signing this informed consent form. \_\_\_\_\_ [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:

Date: / \_/

Signatory's Name:

Signature of the Investigator: \_\_\_\_\_

Date:

Study Investigator's Name:

Subject Number: \_\_\_\_\_

Signature of the Witness

Date: / /

Name of the Witness:

[Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject or his/her attendant.]