ACCUTANE

INFORMED CONSENT/ PATIENT AGREEMENT

To be completed by the patient, parent, or guardian
and signed by the health care provider

Read each item below and initial in the space provided if you understand each item and agree to follow your health care provider's (provider) instructions. A parent or guardian of a patient under age 18 must also read and understand each item before signing the agreement.

Do not sign this agreement and do not take Accutane if there is anything that you do not understand about all the information you have gotten about using Accutane.

1. I, _____,
(Patient's Name)
understand that Accutane is a medicine used to treat severe nodular acne that cannot be cleared up by any other acne treatments, including antibiotics. In severe nodular acne, many red, swollen, tender lumps form in the skin. If untreated, severe nodular acne can lead to permanent scars.

Initials: _____

2. My provider has told me about my choices for treating my acne.

Initials: _____

3. I understand that there are serious side effects that may happen while I am taking Accutane. These have been explained to me. These side effects include serious birth defects in babies of pregnant females (Note: There is a second Informed Consent form for female patients concerning birth defects.)

Initials: _____

4. I understand that some patients, while taking Accutane or soon after stopping Accutane, have become depressed or developed other serious mental problems. Signs of these problems include feelings of sadness, irritability, unusual tiredness, trouble concentrating, and loss of appetite. Some patients taking Accutane have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts). Some people tried to end their own lives. And some people have ended their own lives. There were reports that some of these people did not appear depressed. No one knows if Accutane caused these behaviors or if they would have happened even if the person did not take Accutane. Some people have had other signs of depression while taking Accutane (see #7 below).

Initials: _____

5. Before I start taking Accutane, I agree to tell my health care provider if, to the best of my knowledge, I have **ever** had symptoms of depression (see #7 below), been psychotic, attempted suicide, had any other mental problems, or take medicine for any of these problems. Being psychotic means having a loss of contact with reality, such as hearing voices or seeing things that are not there.

Initials: _____

6. Before I start taking Accutane, I agree to tell my health care provider if, to the best of my knowledge, anyone in my family has ever had symptoms of depression, been psychotic, attempted suicide, or had any other serious mental problems.

Initials: _____

7. Once I start taking Accutane, I agree to stop using Accutane and tell my provider right away if any of the following happen. I:

- start to feel sad or have crying spells
- lose interest in my usual activities
- have changes in my normal sleep patterns
- become more irritable than usual
- lose my appetite
- become unusually tired
- have trouble concentrating
- withdraw from family and friends
- start having thoughts about hurting yourself/myself or taking your/my own life (suicidal thoughts)

Initials: _____

8. I agree to return to see my provider every month I take Accutane to get a new prescription for Accutane, to check my progress, and to check for signs of side effects.

Initials: _____

9. Accutane will be prescribed just for me—I will not share Accutane with other people because it may cause serious side effects, including birth defects.

Initials: _____

10. I will not give blood while taking Accutane or for 1 month after I stop taking Accutane. I understand that if someone who is pregnant gets my donated blood, her baby may be exposed to Accutane and may be born with serious birth defects.

Initials: _____

11 . I have read the brochure *Important Information Concerning Your Treatment with Accutane* and other materials my provider gave me containing important safety information about Accutane. I understand all the information I received.

Initials: _____

12. My provider and I have decided I should take Accutane. I understand that I can stop taking Accutane at any time. I agree to tell my provider if I stop taking Accutane.

Initials:_____

I now authorize my prescriber _____ to begin my treatment with Accutane.

Patient signature _____
Date_____

Parent/guardian signature (if under age 18): _____
Date: _____

Patient Name (print) _____
Patient Address_____
_____ Telephone (_____-_____-_____)

I have

- fully explained to the patient, _____, the nature and purpose of Accutane treatment, including its benefits and risks
- given the patient the brochure for Accutane and asked the patient if he/she has any questions regarding his/her treatment with Accutane
- answered those questions to the best of my ability.

Prescriber signature: _____ Date: