Informed Consent Form

This consent form has two parts. Part I is for all patients (male and female). Part II is only for female patients.

Sign this form only if you understand all the information you have received from your physician about ACCUTANE™ ROCHE® (isotretinoin) (to be retained in physician's office).

PART I: FOR ALL PATIENTS (MALE AND FEMALE)

I have reviewed the information regarding ACCUTANE and listened to my physician and I understand the following:

- ACCUTANE is a medicine used to treat severe acne that cannot be cleared up by other acne treatments including antibiotics. My physician has told me about my choices in treating my acne.
- Serious side effects may happen while I am taking ACCUTANE. These have been explained to me. These side effects include severe birth defects in babies of pregnant females if ACCUTANE is taken during pregnancy. [Female patients must complete Part II of this form.]
- Some patients taking ACCUTANE have become depressed or experienced other mental changes such as feelings of sadness, irritability, unusual tiredness, trouble concentrating, loss of interest in usual activities, withdrawal from family and friends and loss of appetite. Some patients taking ACCUTANE have had thoughts of hurting themselves or ending their lives, tried to end their own lives, or ended their own lives. There have been reports of patients on ACCUTANE becoming aggressive or violent. No one knows if ACCUTANE caused these behaviours or if they would have happened even if the person did not take ACCUTANE. **I must tell my physician immediately if I have such feelings or thoughts**.
- I must tell my physician, before I start ACCUTANE, if I, or any member of my family, has ever had symptoms of depression, any other mental illnesses or attempted suicide, or taken medicine for any of these problems.
- I must return to see my physician as scheduled (every month) to get a new prescription for ACCUTANE and monitor my body's response to ACCUTANE.

I acknowledge that all the above points have been fully explained to me by my physician and that I clearly understand these points and the information on ACCUTANE provided to me.

Patient, Parent or Guardian Signature _____

Address _____ Telephone # _____

Physician Name _____ Date _____

PART II: ONLY FOR FEMALE PATIENTS

I have reviewed the information on ACCUTANE and listened to my physician and I understand the following:

- ACCUTANE can cause severe birth defects in babies of pregnant females if ACCUTANE is taken during pregnancy.
- I must not take ACCUTANE if I am pregnant or may become pregnant during treatment or up to one month after treatment. I am not pregnant now and do not plan to become pregnant during treatment with ACCUTANE or up to one month after stopping ACCUTANE.
- I must have two pregnancy tests prior to starting ACCUTANE and I must wait until the second or third day of my next normal menstrual period before starting ACCUTANE. If my menstrual period is abnormal in length and intensity, I should first contact my doctor.
- I must return to see my physician as scheduled for monthly pregnancy tests.
- I must use effective birth control for at least one month before starting ACCUTANE, during ACCUTANE treatment, and for one month after stopping ACCUTANE. My physician has recommended that I either abstain from sex or use two reliable kinds of birth control at the same time even if I think I cannot become pregnant.
- Birth control methods may fail. No birth control method is absolutely safe. My physician has explained this to me. I must stop taking ACCUTANE and immediately contact my physician if:
  - My menstrual period is delayed during treatment.
  - I become pregnant while taking ACCUTANE or during the month after stopping ACCUTANE.
- I must discuss with my physician the desirability of continuing pregnancy, if I become pregnant.

I acknowledge that all the above points have been fully explained to me by my physician and that I clearly understand these points and the information on ACCUTANE provided to me.

Patient, Parent or Guardian Signature _____

Address _____ Telephone # _____

Physician Name _____ Date _____

For full prescribing information, please consult the ACCUTANE™ ROCHE® Product Monograph.

If you require this information in an accessible format, please contact Roche at 1-800-561-1759.

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