

HFHS CONSENT TO PARTICIPATE IN A RESEARCH STUDY
sample application

PROJECT TITLE:

SWOG 0218, Phase II Study of Oral EGFR Tyrosine Kinase Inhibitor OSI-774 (NSC-718781) in Patients with Malignant Pleural Mesothelioma.

1. PURPOSE OF THE CLINICAL TRIAL

You have been asked to take part in a research study (clinical trial) because you have been diagnosed with malignant pleural mesothelioma. Currently there is no standard treatment for this type of cancer that is very effective. The purpose of this clinical trial is two-fold: 1) to determine how effective the investigational (research) drug OSI-774 is in treating this disease; and 2) to determine what side effects this treatment may cause and how often they occur.

There will be approximately 55 persons in this trial. It is estimated that 3-6 of these patients will be registered within the Henry Ford Health System. This clinical trial is being sponsored by the National Cancer Institute and the Southwest Oncology Group and will also be conducted at other hospitals or medical centers.

2. PROCEDURES OF THE CLINICAL TRIAL

The following tests and procedures may be done to make sure that you are eligible for this study. None of these tests are experimental. They are routine. You may not need to have all these tests done. Depending on when you last had them, you may need to repeat some of these tests:

- Blood tests (equal to 2-4 teaspoons)
- X-ray, CT Scan or MRI

If you are eligible and decide to take part in this study, you will take the experimental drug OSI-774 (tablet) once a day by mouth. You will take this drug every day until your disease worsens or the side effects of this treatment become too dangerous for you to continue.

New information may become available which would suggest that this treatment is either ineffective or the risks involved would be considered greater than the anticipated benefits. If for any reason this treatment is discontinued, your doctor will discuss alternative treatment options with you.

In order to monitor the occurrence of side effects and your disease status during the time you are receiving this treatment and to minimize the discomfort/risks which may be involved, you will have blood tests (equal to 2-4 teaspoons) every four weeks and a CT or MRI scan approximately every eight weeks.

After discontinuing this treatment, lab tests and scans will be performed at the discretion of your physician. A physical exam will be done every six months for the first two years and then annually thereafter for up to three years.

A piece of your tumor which was obtained at the time of your biopsy will be sent for special scientific testing. This testing is for research purposes only, and is being done in an effort to better understand this disease and the treatment being administered. This special testing will in no way affect the treatment you receive on this clinical trial. The biopsy is part of standard procedures for diagnosis. No additional biopsy or procedure will be done for this purpose.

3. RISKS OF THE CLINICAL TRIAL

Certain discomfort and risks may occur from receiving the treatment discussed above. You will probably experience some of the side effects discussed; it is very unlikely that you will experience no side effects. Although the side effects are usually temporary and manageable, it is possible they could last for an indefinite length of time. There is also the risk of experiencing very uncommon or previously unknown side effects. Death may result from the side effects associated with these drugs or drug combinations.

The side effects of the drug OSI-774 include the following:

Likely:

- Fatigue
- Irritation and peeling of your skin
- Dry skin
- Itching
- Skin rash
- Loss of appetite
- Diarrhea
- Dry mouth
- Nausea
- Vomiting
- Muscle weakness
- Dry eyes
- Headache
- Bleeding from the stomach and/or intestine

Less likely but serious:

- Swelling, or irritation in your mouth
- Abnormal liver function
- Eye irritation - which may be more likely if you wear contact lenses

When blood is drawn for laboratory tests or when your treatment infusion is given, you may experience minor discomfort, bleeding, bruising or an infection at the site where a needle or infusions tube was inserted into your skin.

You cannot be in this clinical trial if you are pregnant, breastfeeding a child or trying to become pregnant. If you are pregnant at this time or if you get pregnant before you complete the treatment offered in this trial, there may be increased risks from this treatment to you or your unborn child that cannot now be predicted. There is the possibility of long-term effects of this treatment on your ability to become pregnant or risks to future offspring. You must use effective birth control methods during the time you are receiving this treatment and for a three-month time period following completion of this treatment. If you are of childbearing potential, you may be asked to have a pregnancy test before you begin participation in this clinical trial.

If you father a child during the time you are receiving this treatment or during the three-month time period following the completion of this treatment, there may be increased risks to that child that cannot now be predicted. There is the possibility of long-term effects of this treatment on your ability to father a child or risks to future offspring. You have been instructed that either you or your partner must use effective birth control methods during the time you are receiving this treatment and for a three-month time period following the completion of this treatment.

This clinical trial may have risks that are not known at this time. You will be told about any information that is discovered that might affect your willingness to continue being in the trial.

You have told the person obtaining your consent about any other medical research projects in which you are involved.

4. BENEFITS OF THE CLINICAL TRIAL

There is no guarantee that you will benefit from your participation in this clinical trial, and the treatment you receive may even be harmful. However, it is hoped that this treatment will either slow or stop the growth of your disease or cause it to disappear.

There may be no direct benefit to you, however, information from this trial may benefit other patients with similar medical problems in the future.

5. ALTERNATIVE TO PARTICIPATION

The treatment alternatives should you decide not to participate in this clinical trial, include standard chemotherapy drugs and/or radiation therapy other investigational treatments or no active treatment, but rather supportive care for the management of the symptoms you may be experiencing as a result of your disease. These alternative treatments have been discussed with you prior to your participation in this clinical trial and you have been given the opportunity to ask questions which you have indicated have been answered to your satisfaction.

6. PRIVACY

Information from this clinical trial that identifies you by name will be private. No one outside of your doctor's office or hospital, except for the United States Food and Drug Administration (FDA), can see any information about you unless you give your permission in writing or unless there are legal requirements that require that your records be made available. If information from this trial is published in a medical journal or presented at a scientific meeting, you will not be identified by name.

However, because this clinical trial is sponsored by the National Cancer Institute and the Southwest Oncology Group, representatives of those organizations might see your medical record. You hereby consent to this review and also to the release of copies of your radiology studies, laboratory and pathology specimens and medical records as necessary for the evaluation of your participation in this clinical trial. Information as to your disease status will be requested and reviewed on a regular basis after you have completed all treatment on this trial

7. INJURY DUE TO CLINICAL TRIAL

If you have a medical problem as a result of being in this clinical trial, you should call Dr. Robert Chapman at (313) 916-1850. If you have a medical emergency as a result of participating in this trial while at Henry Ford Hospital and Medical Centers, emergency treatment will be given to you. If the adverse reaction, illness or injury happens somewhere else, you should go to an emergency room. You and/or your medical insurance may have to pay for medical care if you are injured as a result of participating in this clinical trial. There is no federal, state or other program that will compensate you or pay for your medical care if you are injured as a result of your participation in this clinical trial.

8. INFORMATION ABOUT THE CLINICAL TRIAL

DR. _____ has explained this clinical trial to you and has offered to answer any questions you have. If you have additional questions about the research, you may contact Dr. _____ at _____. If you have questions about your rights as a research subject, you may contact the Research Office at Henry Ford Hospital at (313) 916-2024.

You will be informed about important new information that comes from this trial.

9. VOLUNTARY PARTICIPATION

You do not have to be a part of this clinical trial. Your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this trial at any time without penalty or loss of other benefit to which you are entitled. You will get the same medical care from Henry Ford Hospital or Medical Centers that you would have had without consenting to participate in this clinical trial.

10. STOPPING THE TRIAL

You will be told if there is any new information that might make you want to stop being in this clinical trial. The person in charge of the trial or your doctor can end your part in the clinical trial at any time. You can stop participating in this clinical trial anytime you want. Due to the fact that the chemotherapy used in this study is experimental, even if this treatment helps you, you might not be able to continue this type of chemotherapy when the study is complete.

11. COST TO THE SUBJECT

OSI-774 will be supplied by the Sponsor free of charge to patients participating in this clinical trial. In the event that this drug becomes commercially available, you or your insurance company may need to assume responsibility for the costs associated with this treatment.

12. CONSENT

You have read this consent form or this consent for has been read to you and you have indicated that you understand it. You have indicated that you understand what you will be asked to do. You have indicated that your questions have been answered. You agree to be in this clinical trial.

You have been given a copy of this consent form.

Signature of Subject

Date

Print Name of Subject

Witness' Signature

Date

Investigator's Signature

Date