

CONSENT FORM
SAFINUR™ Pilot Clinical Study

You are invited to participate in a research study of SAFINUR™, a naturally-derived compound patented worldwide for its anti-tumor properties. You were selected as a possible participant by your health care practitioner because of your medical history. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted with the cooperation of your health care practitioner. It is being sponsored by SAFICOR, the company that studied and patented the active compound in SAFINUR™ as an anti-tumor agent.

DISCLAIMER: SAFICOR DOES HEREBY DISCLAIM ANY AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, WITH RESPECT TO SAFINUR™, INCLUDING ANY REPRESENTATION OR WARRANTY OF QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE, OR THAT THE USE OF SAFINUR™ FOR PURPOSES OTHER THAN SPECIFIED IN THIS AGREEMENT WILL NOT INFRINGE THE RIGHTS, PATENT OR OTHERWISE, OF ANY THIRD PARTY.

STUDY PURPOSE

The purpose of the study is to determine 1) how well is SAFINUR™ tolerated (i.e. monitoring of side effects) 2) the efficacy of SAFINUR™ against a variety of human tumors, especially those that have not responded well to other treatments and/or are in advanced stages.

STUDY PROCEDURES

If you agree to participate in this study:

- 1. Tell your health care practitioner you want to participate** so he/she can give you the appropriate forms and informational brochure.
- 2. Sign this consent form** ONLY after reading the detailed information about SAFINUR™. It is very important you understand the information presented. If you have any questions, discuss them with your health care practitioner before signing this consent form.
- 3. Sign the appropriate release form** so that your health care practitioner may obtain the relevant portions of your medical records from other doctors/institutions (if applicable). This includes doctor notes, previous treatments (radiation, chemotherapy, etc), biopsies, laboratory tests, scans, MRIs, x-rays, pathology and surgical reports.
- 4. Answer initial questionnaire** about medical history as well as current symptoms relevant to the study (2 pages).
- 5. Agree to have an initial monitoring procedure** (CT scan or PET scan or MRI or bone scan or blood test, as applicable to your individual case) before starting SAFINUR™. This is to establish the exact condition you were in at the beginning of the study. It is very likely that you already underwent these procedures in the course of your disease because they are part of standard medical care. You may not need to undergo a new procedure if it was done within the last month. The cost of these procedures is not covered by SAFICOR or your health care practitioner.
- 6. Agree to follow the instructions** for participating in the study. These instructions include:
 - a. Store SAFINUR™ bottles properly after receiving them.
 - b. Take SAFINUR™ as directed, daily, throughout the length of the study (4-6 months). It is important that you do not interrupt the intake of SAFINUR™ to maximize its effects.
 - c. Follow diet modifications as explained in the instruction sheet.
 - d. Answer a one-page questionnaire on side effects (once a month) and return to your health practitioner.
 - e. Communicate regularly with your health care practitioner regarding your progress.

Patient's initials: _____

7. Agree to have another monitoring procedure (CT scan or PET scan or MRI or bone scan or blood test, as applicable to your individual case) approximately 3-4 months after starting SAFINUR™. This is to establish your response to SAFINUR™. You may also need to undergo a final monitoring procedure at the conclusion of the study (6+ months).

8. Arrange to release any results of any new monitoring procedures (CT scan or PET scan or MRI or bone scan or blood test, as applicable to your individual case) to your health care practitioner.

Other relevant information:

- * You will **not** be given any placebo (inactive sugar pill). You will receive SAFINUR™ as a dietary supplement.
- * You will **not** be assigned to any groups. You participate as an individual.
- * You do **not** need to attend any special meetings.
- * You can take SAFINUR™ at home.
- * You may lead a normal life throughout the duration of the study. However, you may need to modify your diet as discussed in the instruction sheet.
- * You and your health care practitioner will determine how often you need to communicate (as relevant to your case).
- * You and your health care practitioner will determine how often you need to go for office visits (as relevant to your case).
- * You and your health care practitioner will determine the pros- and cons- of withholding standard treatment (if applicable) while on SAFINUR™. Your decision should be based on this discussion.
- * At the conclusion of the study, SAFINUR™ will continue to be available to you through your health care practitioner. When the clinical study ends, the price may vary from what you paid during the study.

TOXICITY STUDY INFORMATION: The active component in SAFINUR™ is a uniquely non-toxic compound with a well-studied safety record determined by LD50 and other toxicity studies.

1) LD50 toxicity studies: LD50 (lethal dose 50%) refers to the amount of a substance expected to kill 50% of the test animals used in a controlled study. It is typically expressed in mg of material per kg of body-weight. The following table shows oral or intravenous injection LD50 values in rats or mice for a variety of common substances as well as some chemotherapy agents (chemo). A large LD50 means that the substance has little toxicity. Small LD50 values indicate the substance is very toxic.

<i>Name of Substance</i>	<i>LD50 (mg/kg)</i>
Aspirin [oral]	1000
Ibuprofen (Advil) [oral]	636
Caffeine [oral]	192
Cyclophosphamide (chemo) [oral]	144
Nicotine (found in tobacco) [oral]	53
Etoposide (chemo) [IV injection]	15
Paclitaxel (chemo) [IV injection]	12
Taxol (chemo) [IV injection]	12
Cisplatin (chemo) [IV injection]	11
5'-fluorouracil (chemo) [IV injection]	10
Doxorubicin (chemo) [IV injection]	10
Arsenic (rat poison) [oral]	8
Cyanide (poison) [oral]	6.2
Vincristine (chemo) [IV injection]	1-3
Vinblastine (chemo) [IV injection]	1-3

Patient's initials: _____

LD50 studies with the active component in SAFINUR™ were conducted as follows: Male albino mice weighing 20±1.5 g were fasted from food for 24 hr prior to experiment but were given water *ad libitum*. Each experimental group consisted of 6 mice. Animals of the different groups were injected intraperitoneally with the active component in SAFINUR™ in increasing doses of 100-1000 mg/kg body weight. The active component in SAFINUR™ was applied in concentrations of 1, 5, and 10%; the volume of the solution injected was of the order of 1ml/100g body weight. The animals were observed in the course of seven days. **The active component in SAFINUR™ did not provoke lethality and exerted no toxic effects and thus an LD50 and the toxic doses could not be determined.**

2) Other toxicity studies:

- a) **Cat Study:** The active ingredient in SAFINUR™ was injected intravenously to five cats in doses of 10, 20, 30, 40 and 50 mg/kg. No short or long-term toxicity was noticed.
- b) **Rat Study:** Three groups of ten male Wistar rats weighing 250-300g received intravenous injections of the active ingredient in SAFINUR™ of 10, 20 and 30 mg/kg. No acute or long-term toxicity was observed.
- c) **Rabbit Study:** Twenty four rabbits weighing between 2 and 2.5 kg were divided in 3 groups, each receiving 10, 20 or 30 mg/kg of the active ingredient in SAFINUR™ intravenously. No acute or long-term toxicity was observed.
- d) **Dog Study:** Four male dogs weighing 27, 26, 19 and 19 kg were given the active ingredient in SAFINUR™ at 10 and 30 mg/kg in a volume of 0.3 ml/kg into vein saphina of one of the hind legs. Two dogs had no signs of toxicity. One of the dogs vomited 75 min. after the injection. Another showed signs of allergic reaction (itching, red eyes) which disappeared within 1.5- 2 hrs. No long-term effects were observed.

THE STUDY HAS THE FOLLOWING RISKS:

1. Experience side effects. Based on previous case reports from individuals who took SAFINUR™, the most common side effects are:

a. Stomach irritation. Approximately 70% of patients have experienced stomach irritation (burning, indigestion) if capsules are taken on an empty stomach or without enough water. To decrease the likelihood of stomach irritation, take SAFINUR™ with meals. If SAFINUR™ is taken with meals, the likelihood of having stomach irritation is less than 10%. Stomach irritation may be further reduced by using over-the-counter anti-acids (mainly baking soda).

b. Nausea/vomiting. Approximately 30% of patients have suffered mild to moderate nausea, mostly in the first 2-3 days after starting SAFINUR™. About 10% of patients have experienced vomiting. Nausea/vomiting usually occur if capsules are taken on an empty stomach or without enough water. If SAFINUR™ is taken with meals, the likelihood of having nausea/vomiting is less than 20%.

c. Diarrhea. Approximately 50% of patients have suffered mild to moderate diarrhea, mostly in the first three days after starting SAFINUR™. More than 95% of patients improved after the initial period and the diarrhea ceased.

d. Bleeding of existing hemorrhoids. Approximately 1% of patients have experienced mild to moderate bleeding of existing hemorrhoids. If you have hemorrhoids prior to entering the SAFINUR™ study, make sure to tell your health care practitioner.

e. Lowering blood pressure (if you already have high blood pressure). About 50% of patients that already had high blood pressure experienced a decrease in blood pressure, getting closer to normal. If you are taking blood pressure medication, you may need to consult your doctor for dose re-adjustment. SAFINUR™ intake did not decrease blood pressure in patients with normal or low blood pressure.

f. Lowering blood sugar (if you already have high blood sugar). About 35% of patients that already had high blood sugar experienced a decrease in blood sugar, getting closer to normal. If you are taking blood sugar medication, you may need to consult your doctor for dose re-adjustment. SAFINUR™ intake did not decrease blood sugar in patients with normal or low blood sugar.

Patient's initials: _____

g. Lowering blood cholesterol and triglycerides (if you already have **high** blood cholesterol/triglycerides). About 60% of patients that already had high blood cholesterol/triglycerides experienced a decrease in blood cholesterol/triglycerides, getting closer to normal. If you are taking blood cholesterol/triglycerides medication, you may need to consult your doctor for dose re-adjustment. SAFINUR™ intake did not decrease blood cholesterol/triglycerides in patients with normal or low levels.

h. Decreasing arthritis and back pain (if you already arthritis and back pain). About 40% of patients that already had arthritis/back pain experienced a decrease in pain. If you are taking arthritis or other pain medication, you may need to consult your doctor for dose re-adjustment.

i. If you and your health care practitioner decide to withhold standard treatment while on the study, it is possible that you will be denying yourself any benefits that treatment might have provided. However, if throughout the course of the SAFINUR™ study, it is determined that you are not responding favorably to SAFINUR™, you can resume standard treatment as recommended by your health care practitioner.

2. Experience an allergic reaction. Like any other substance, it is possible, though highly unlikely (less than 1% chance), that sensitive individuals may experience an allergic reaction characterized by any of the following symptoms: itching, sneezing, coughing, difficulty breathing, watery eyes, itchy eyes, red eyes. If the allergic reaction occurs, it is most likely occur after taking SAFINUR™ for the first time, within 1 hour of ingestion. If this occurs, discontinue use and notify your health care practitioner.

3. Interference with standard chemotherapy. If you undergo chemotherapy while using SAFINUR™, it is possible (but not likely) that SAFINUR™ may interfere with chemotherapeutic action. Determining the possibility of interaction/interference between SAFINUR™ and any one chemotherapy drug is practically impossible. Please discuss this possibility with your healthcare practitioner if you decide to continue chemotherapy while on the SAFINUR™ study. Keep in mind that *it is also possible that standard chemotherapy may interfere with the action of SAFINUR™ and reduce/eliminate its possible beneficial effect.* This is known for at least one chemotherapy agent (Gleevec) that reduces entry of the active compound in SAFINUR™ into tumor cells, lowering its efficacy.

4. Lack of response. It is possible that your tumor may not respond to SAFINUR™ within the study period.

5. Special note regarding pregnancy: Even though laboratory mice given SAFINUR™ did not demonstrate any reproductive problems and bore normal offspring, the effects of SAFINUR™ on human pregnancy are not known. Therefore, it is highly recommended that you discuss this issue with your health care practitioner if you are or want to become pregnant.

BENEFITS OF STUDY PARTICIPATION

The potential benefits to study participation are:

1. Possibility of stopping tumor growth. Based on previous case reports from individuals who took SAFINUR™, your tumor(s) may stop growing if SAFINUR™ is taken consistently and according to instructions for the duration of the study. If SAFINUR™ intake is interrupted prematurely, you may significantly decrease your chances of stopping tumor growth.

2. Possibility of stopping tumor metastasis (spreading). Based on previous case reports from individuals who took SAFINUR™, your tumor(s) may stop spreading if SAFINUR™ is taken consistently and according to instructions for the duration of the study. If SAFINUR™ intake is interrupted prematurely, you may significantly decrease your chances of stopping tumor spreading.

3. Possibility of reducing tumor size. Based on previous case reports from individuals who took SAFINUR™, your tumor(s) may shrink if SAFINUR™ is taken consistently and according to instructions for the duration of the study. If SAFINUR™ intake is interrupted prematurely, you may significantly decrease your chances of decreasing tumor size.

Patient's initials: _____

4. Possibility of tumor disappearance. Based on previous case reports from individuals who took SAFINUR™, your tumor(s) may disappear if SAFINUR™ is taken consistently and according to instructions for the duration of the study. If SAFINUR™ intake is interrupted prematurely, you may significantly decrease your chances of causing tumor disappearance.

5. Possibility of opening other medical interventions that were previously considered impossible. This is particularly important in the case of very large/multiple invasive tumors that were considered inoperable because of tumor spreading to surrounding (normal) tissues and organs. If the tumor responds to SAFINUR™ by stopping growth and metastasis and detaches from surrounding tissue, it is possible that a surgeon may be willing to remove it.

6. Lowering blood pressure (if you already have high blood pressure). About 50% of patients that already had high blood pressure experienced a decrease in blood pressure, getting closer to normal. If you are taking blood pressure medication, you may need to consult your doctor for dose re-adjustment. SAFINUR™ intake did not decrease blood pressure in patients with normal or low blood pressure.

7. Lowering blood sugar (if you already have high blood sugar). About 35% of patients that already had high blood sugar experienced a decrease in blood sugar, getting closer to normal. If you are taking blood sugar medication, you may need to consult your doctor for dose re-adjustment. SAFINUR™ intake did not decrease blood sugar in patients with normal or low blood sugar.

8. Lowering blood cholesterol and triglycerides (if you already have high blood cholesterol/triglycerides). About 60% of patients that already had high blood cholesterol/triglycerides experienced a decrease in blood cholesterol/triglycerides, getting closer to normal. If you are taking blood cholesterol/triglycerides medication, you may need to consult your doctor for dose re-adjustment. SAFINUR™ intake did not decrease blood cholesterol/triglycerides in patients with normal or low levels.

9. Decreasing arthritis and back pain (if you already arthritis and back pain). About 40% of patients that already had arthritis/back pain experienced a decrease in pain. If you are taking arthritis or other pain medication, you may need to consult your doctor for dose re-adjustment.

Alternatives to Study Participation

You may refuse participation in this study for any reason at any time. You may undergo other conventional medicine or alternative medicine treatments.

Voluntary Nature of the Study

Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with your health care practitioner. If you decide to participate, you are free to withdraw at any time without affecting those relationships.

Study Costs/Compensation

Because SAFICOR (study sponsor) is a small business entity, it is allowed to recover its costs for patenting, producing and providing SAFINUR™ by charging clinical study participants. However, this amount is significantly lower than its retail value. Study cost depends on dose; dose depends on body weight and tumor load.

Research Related Injury

SAFICOR is not responsible for any injury that may result from this research activity. Any necessary treatment, including first aid, emergency treatment and follow-up care as needed is the entire responsibility of the patient. Payment for care for such injuries is your responsibility. If you think that you have suffered a research-related injury, let your health care practitioner know right away.

Patient's initials: _____

Confidentiality

1. Your medical records: the records of this study will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject. Your record for the study may, however, be accessed and reviewed by your health care provider, the study sponsor (SAFICOR), the institutional review board (IRB), and the *Food and Drug Administration (FDA)*. To these extents, confidentiality is not absolute.

2. Identity and dosage of SAFINUR™: the patient needs to agree to keep private the identity of SAFINUR™ as well as the dosage used in the study. This includes any personal, phone, written, electronic or media communication during the study or after the study is completed. This is necessary to ensure that other patients that may enroll in the study receive accurate information from the right source (health care practitioner and/or study sponsor). However, if the patient has friends and relatives whom may benefit from SAFINUR™, they should contact the study health care practitioner or the study sponsor (SAFICOR) to determine if they qualify for enrollment in the study.

Contacts and Questions

SAFICOR, the study sponsor, has designated Mr. Sad Wardak as the Clinical Study Coordinator. He is the main contact person for any questions regarding the study that have not been answered by your health care practitioner. You may ask any questions you have now, or if you have questions later, you are encouraged to contact him at 714-532-4632; best hours to call are 11-7pm pacific standard time. You can also e-mail the scientific team if you have scientific questions at scientist@safinur.com. You can keep this form for your records. **Please sign the last page confirming your consent and fax it to 801-729-5310 or send it through regular US mail** to: SAFICOR 1920 E. Katella Avenue Suite U, Orange, CA 92867; USA.

Statement of Consent

I have read and understood the above information. I have asked questions to my health care practitioner and have received satisfactory answers. I consent to participate in the SAFINUR™ clinical study.

Signature of patient _____

Name of patient _____

Address: _____

Telephone and e-mail: _____

Date _____

Signature of health care practitioner _____

Name of health care practitioner _____

Address: _____

Telephone and e-mail: _____

Date _____

Signature of Witness _____

Name of witness _____

Address: _____

Telephone and e-mail: _____

Date _____