The Stehlin Foundation
For Cancer Research **Informed Consent**

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH OF DESMOPLASTIC SMALL ROUND CELL TUMOR

Collection of tumor samples for research

Subtitle:

1. _____ **Approved on:_____**
Participant's Name **I.D. Number:_____**
(Above 2 items filled in by Stehlin Study Coordinator)

You are being asked to take part in this research study at The Stehlin Foundation for Cancer Research (hereinafter referred to as "TSFFCR" or "the institution"). This research study is strictly voluntary. This consent form explains why we are performing this research study and what your role will be if you choose to participate. This form also describes the possible risks connected with being in this study. After reviewing this information with the person responsible for your enrollment, you should know enough to be able to make an informed decision on whether you want to participate in the study. This study complies with all laws and regulations that apply.

You are being asked to take part in this study because you have DSRCT (Desmoplastic Small Round Cell Tumor).

DESCRIPTION OF RESEARCH

2. PURPOSE OF STUDY

Treatment: The purpose of this research study is to:

- Grow DSRCT human cancers as xeno-transplants in nude mice.
- Test anti-cancer agents and/or treatments on these human tumors in the nude mice with the purpose of finding better treatments for these DSRCT tumors.

Procedures: Study participants will be asked for a small sample of their tumor during a tumor removal or biopsy. About 10 participants will be enrolled per year.

3. DESCRIPTION OF RESEARCH

Treatment: This is an investigational study. Study procedures will be performed free of charge. Study participants will not receive any financial compensation

Procedures: Participants who agree will have a small sample of their tumor collected during tumor removal or biopsy and will have this tumor sample researched at TSFFCR.

4. RISKS, SIDE EFFECTS, AND DISCOMFORTS TO PARTICIPANTS

Treatment: The only physical risk is that associated with the tumor removal or biopsy, which is not covered under this Informed Consent. There are no physical risks associated with the research performed by TSFFCR. The only potential risk is accidental release of information. To protect the participant's privacy, all samples used for research are coded to maintain patient confidentiality and kept in secure and confidential tissue banks. No research results are placed into the participant's medical records.

5. POTENTIAL BENEFITS

Treatment: Participation in the study may help researchers to discover information that may benefit the patient and/or future patients in the treatment of DSRCT.

6. ALTERNATE PROCEDURES OR TREATMENTS

Treatment: You may choose not to take part in this study.

I understand that the following statements about this study are true:

7. According to the institutional conflict of interest policy the principal investigator, Dr. Beppino C. Giovanella, does not have a financial interest in any aspect of this research.

8. My participation is voluntary.

9. I may contact the principal investigator for this study, Dr. Beppino C. Giovanella, at 713-756-5750 with any questions that have to do with this study.

10. I understand that the study may be changed or stopped at any time by the principal investigator of TSFFCR**.**

11. The institution will take appropriate steps to keep my personal information private. However, there is no guarantee of absolute privacy.

12. I understand that I will not receive reimbursement of expenses or financial compensation from the institution.

13. Any and all costs associated with tumor removal or biopsy will be the responsibility of the patient. All of the costs connected with this study performed at TSFFCR will be covered by TSFFCR, and there will be no cost to the patient for the study of their tumor.

14. I recognize that there are no plans to provide any compensation to me for any patents that may result from my participation in this research.

Authorization for Use and Disclosure of Protected Health Information

A. During the course of this study, the research team at TSFFCR will be collecting information about you that they may share with the FDA and/or the NCI. This information may include any results or studies in working with your tumor.

   Your doctor and the research team may share study information with certain individuals. These individuals may include representatives of the FDA, and/or individuals who put all the study information together in report form. The TSFFCR research team may provide this information to the FDA at any time. There is no expiration date for the use of this information as stated in this authorization.

B. You may withdraw your authorization to share this information at any time in writing. For more information on how to do this, please contact the Dr. Beppino Giovanella, Stehlin Foundation, 1918 Chevenert, Houston, TX, phone 713-756-5750.

C. If you refuse to provide your authorization to disclose this protected health information, you will not be able to participate in the research project.

D. I understand that my personal health information will be protected according to state and federal law. However, there is no guarantee that my information will remain confidential, and may be re-disclosed at some point.

CONSENT/AUTHORIZATION FOR TUMOR TISSUE DONATION
(Mark choice with an "X")

I elect to ____ or not to ___ release discarded tissue or biopsy to TSFFCR.
Patient's Initial___

Having read and understood the above, and having had the chance to ask questions about this study and reflect and consult with others, I give _____ Permission to enroll me on this study. I have been given a copy of this consent.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____ _____
WITNESS OTHER THAN PHYSICIAN OR INVESTIGATOR DATE

_____ _____
SIGNATURE OF PERSON RESPONSIBLE AND RELATIONSHIP DATE

I have discussed this research study with the participant and/or his or her authorized representative, using a language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
SIGNATURE OF STUDY DOCTOR OR PERSON OBTAINING CONSENT DATE

ASSENT/AUTHORIZATION OF MINOR

I have been given an explanation of the research to be performed under this Informed Consent. I understand the research and have had the chance to ask questions about this study and reflect and consult with others. I give TSFFCR permission to enroll me on this study. I have been given a copy of this consent.

_____ _____
SIGNATURE OF MINOR DATE

I was present during the explanation of the research to be performed under this study. The child participant was also present. In my opinion, the child assented to the participation in the research.

_____ _____
SIGNATURE OF WITNESS DATE

Translator

I have translated the above informed consent into _____ for this Participant. (Name of Language)

_____ _____ _____
NAME OF TRANSLATOR SIGNATURE OF TRANSLATOR DATE