

## Pathway Healing Center, Inc.

### Informed Consent Agreement

I, Audrey M. Snow, state that I am 74 years of age and I wish to participate in a program of medical research being conducted by Pathway Healing Center, Inc.

The purpose of the research is to investigate the effects of Stimulated Autologous Immune Serum on cancer growth. Tumor and immunologic parameters will be monitored. The primary purpose of the study is the therapeutic effect of Stimulated Autologous Immune Serum on cancer growth. The investigational procedure is the use of Stimulated Autologous Immune Serum in cancer therapy. Cells, plasma, and tissues may be banked for later study.

My doctors have discussed the nature of my disease, the failure of my cancer to respond to usual therapies, and the results of accepted treatment. It is hoped that I will benefit from this treatment, but it is not to be considered curative. There is no known curative treatment at this time for my disease.

I understand that I will return monthly for further examination, testing, and treatment.

Minor personal risks include pain, bruising or bleeding at the site where blood is drawn, biopsies are performed, or injections given. Fever and chills may follow the use of Stimulated Autologous Immune Serum.

Major personal risks include radiation exposure from x-rays; allergy to materials used to stimulate the autologous cells and serum products produced by the stimulation to include a fatal reaction; low white counts and/or platelet counts; anemia; fluid retention, shortness of breath, rapid heart beat, kidney or liver damage from serum produced in the stimulation process. Every effort will be taken to minimize adverse effects (side effects) but I understand they are unpredictable in both nature and severity.

I understand I will receive accepted medical care if required even if I do not participate in this study. Alternative procedures, which may benefit me personally, include interferon, radiation, or systemic chemotherapy. I understand that all these procedures are palliative and not cures for cancer, and that should I agree to participate, I will be foregoing the opportunity for these alternative treatments only while I participate in this study.

Volunteer initials: AMS

I understand I am free to withdraw from this protocol before treatment begins without prejudicing continuing medical care.

I have a right to privacy and all information obtained in connection with this study and that can be identified with me will remain confidential. I understand that clinical and laboratory data collected on me will be used in analyzing the results of Stimulated Autologous Immune Serum. Information may be released to the Food and Drug Administration and to the National Institutes of Health. The results of this study may be published in scientific journals without identifying me by name.

I understand and accept that additional research costs (costs which are beyond those required for usual diagnosis and treatment) may be incurred by me and that I will be responsible for these expenses.

Every effort will be made to prevent injury that could result from this research. Compensation for injuries as a result of participating in this study is not available except as may be required by law.

In the event of my death during this procedure I consent to a full autopsy.

My signature below is to certify that I have read this document, have had a full opportunity to discuss it with my doctors, and consent to the use of Stimulated Autologous Immune Serum. I understand that I may ask further questions at any time and that I may have a copy of this document. I understand the procedure is not a proven treatment for cancer.

Please initial each page of the consent form and sign below.

Witness: Lucia Duncan Volunteer: Andrew M. Snow

Date: 2/25/99 Date: 2-25-99

I have explained the preceding to the patient. This consent form includes no exculpatory language through which the patient is made to waive any legal right or to release the investigator from liability for any negligence.

Investigator: Roy C. Payne MD

Date: 2-25-99

Volunteer initials: \_\_\_\_\_

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