APPENDIX I

OUTLINE OF SAMPLE CONSENT FORM - "Digitalis Investigation Group"

Local Center Name _____ Randomization No.:

Patient Name _____ - - - / - - - -

You have been found to have heart failure which means that the heart does not pump blood adequately. The symptoms of heart failure include leg swelling and shortness of breath Digitalis is a drug that has been commonly used for more than 200 years to treat patients with heart failure. In spite of this, it is unclear whether digitalis is beneficial, harmful, or has no effect in most patients with this condition. The National Heart, Lung and Blood Institute and the Department of Veterans Affairs are, therefore, conducting a large research study in the U.S. and Canada. The aim of this study is to find out whether or not the use of digitalis prolongs or shortens life and reduces symptoms.

You will have an equal chance of receiving digitalis or placebo; neither you nor your doctor will know which. You will be asked to take one, two, three or four tablets a day. All tablets are to be taken together once a day. Digitalis can occasionally cause side effects which are rarely serious but can sometimes be bothersome. The side effects include nausea, vomiting and rarely irregular heart rhythm. If side effects occur your doctor may stop or decrease the drug The treatment may or may not be of personal benefit for you but the information gathered from the study will be very important for the treatment of patients with heart failure,

If your heart failure worsens your doctor will re-evaluate your treatment. You will always be offered any treatment that your clinical condition requires and participating in this study will not affect that. Any extra tests required by the study will be free of charge.

Study visits will be scheduled about three times a year and would usually coincide with your regular visits to your physician. At the visits, information about your medical history will be collected and a brief physical examination will be made. Participation in this study will not prolong your usual visit to your physician. Each visit will take at out 15 minutes. The study is currently scheduled to conclude in 1995.

Your Social Security or Medicare number may be used to help the clinic know if you have needed hospital care. All information obtained as part of the study will be confidential and only used for research purposes. Your identity and social security number will be kept confidential within the liits of the law.

Your participation in the study is entirely voluntary and will not 'affect any medical care to which you are entitled. An alternative to participation is continued individualized care by your physician. You are free to refuse to participate or withdraw from the study at any time without penalty. If you have any questions please contact Dr. _____ at this telephone number _____. Questions about research related risks can be answered by _____ at this telephone number _____.

[A clinic specific statement regarding compensation related to participation as a human research subject should be inserted here. Generally, the study does not provide compensation for medical injury.]

I agree to pat-tic ipate in the digitalis study and I have been given a copy of this form.

_____ _____
Patient's Signature Date

_____ _____
Witness' Signature Date

_____ _____
Participating Investigator's Signature Date

(This page revised 10/91.)