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(INSTITUTION)

CONSENT TO PARTICIPATE AS A RESEARCH SUBJECT IN THE SYSTOLIC HYPERTENSION IN THE ELDERLY PROGRAM

I AGREE TO PARTICIPATE IN A STUDY OF SYSTOLIC HYPERTENSION IN THE ELDERLY WHICH IS SCHEDULED TO CONCLUDE IN 1991. I HAVE BEEN FOUND TO HAVE ISOLATED SYSTOLIC HYPERTENSION, WHICH IS A FORM OF HIGH BLOOD PRESSURE, AND I UNDERSTAND THAT PERSONS WITH HIGH BLOOD PRESSURE ARE MORE LIKELY TO SUFFER FROM HEART ATTACK, STROKE, KIDNEY FAILURE AND EARLY DEATH THAN THOSE WHO HAVE NORMAL BLOOD PRESSURE.

DOCTORS DO NOT AGREE ABOUT WHETHER THE FORM OF HIGH BLOOD PRESSURE I HAVE SHOULD BE TREATED IN PERSONS WHO ARE AT LEAST 60 YEARS OLD. THE PURPOSE OF THE SYSTOLIC HYPERTENSION IN THE ELDERLY PROGRAM IS TO EVALUATE WHETHER TREATMENT FOR THIS FORM OF HIGH BLOOD PRESSURE REDUCES THE CHANCE OF STROKE IN PERSONS AT LEAST 60 YEARS OF AGE.

STUDIES HAVE SHOWN THAT IT IS HELPFUL TO TREAT OTHER FORMS OF HIGH BLOOD PRESSURE IN MIDDLE-AGED PERSONS, AND IT IS POSSIBLE THAT SUCH TREATMENT CAN BENEFIT ME DIRECTLY. THIS STUDY PROVIDES ME WITH AN OPPORTUNITY TO PARTICIPATE IN RELEVANT RESEARCH AND TO CONTRIBUTE TO MEDICAL KNOWLEDGE. THE INFORMATION GATHERED IN THIS STUDY WILL BE VERY IMPORTANT FOR DOCTORS IN DECIDING WHETHER TO TREAT PERSONS MY AGE WITH ISOLATED SYSTOLIC HYPERTENSION.

THE TYPE OF DRUG I WILL BE TAKING IS SELECTED BY CHANCE RATHER THAN BY THE CLINIC DOCTOR, AND I HAVE A 1 IN 2 CHANCE OF RECEIVING AN INACTIVE PILL, CALLED A PLACEBO. NEITHER THE CLINIC DOCTOR NOR I WILL KNOW WHAT DRUG I AM TAKING, ALTHOUGH IN CASE OF AN EMERGENCY IT CAN BE REVEALED.

I WILL BE TAKING PILLS ONCE A DAY, AND THE DRUGS CAN CAUSE SIDE EFFECTS WHICH ARE RARELY SERIOUS BUT CAN BE BOTHERSOME. I COULD EXPERIENCE SUCH SIDE EFFECTS AS: DROWSINESS, TIREDNESS, WEAKNESS, DRY MOUTH, IMPOTENCE, AND NASAL STUFFINESS. RARELY, DEPRESSION, A SLOW PULSE, A REDUCTION IN HEART FUNCTION OR ASTHMA MAY OCCUR. IF THIS HAPPENS, MY TREATMENT MAY BE CHANGED.

I ALSO UNDERSTAND THAT SAFETY PRECAUTIONS HAVE BEEN SET UP TO ENSURE THAT IF MY BLOOD PRESSURE IS TOO HIGH OR TOO LOW, MY TREATMENT MAY BE CHANGED.

Participant's Initials _____

DURING THE STUDY, I AGREE TO VISIT THE CLINIC AT LEAST EVERY THREE MONTHS FOR FOLLOW-UP EXAMS AND PRESCRIPTION REFILLS. AT ALL VISITS, THE FOLLOWING WILL TAKE PLACE:

1. MY BLOOD PRESSURE WILL BE MEASURED THREE TIMES.

2. MY PULSE AND WEIGHT WILL BE MEASURED.

3. I WILL BE ASKED QUESTIONS ABOUT ANY SIDE EFFECTS I MAY HAVE.

4. I WILL BE GIVEN A BRIEF PHYSICAL EXAMINATION, IF NECESSARY.

AT CERTAIN FOLLOW-UP VISITS THE FOLLOWING MAY BE DONE:

1. BLOOD MAY BE DRAWN FROM MY ARM WITH A NEEDLE FOR TESTING. I UNDERSTAND THAT THE NEEDLE FEELS LIKE A PINPRICK; OCCASIONALLY BRUISING OR, VERY RARELY, INFECTION MAY RESULT.

2. SOME OF THE PSYCHOLOGICAL TESTS MAY BE REPEATED.

ALL OF THESE PROCEDURES TOGETHER SHOULD TAKE ABOUT ONE HOUR.

AT THE END OF EACH YEAR, I WILL RECEIVE A MORE COMPLETE EXAMINATION, TO INCLUDE THE FOLLOWING:

1. I WILL BE GIVEN A GENERAL PHYSICAL EXAM BY THE DOCTOR.

2. I WILL BE ASKED MORE QUESTIONS ABOUT BY MEDICAL HISTORY.

3. BLOOD WILL BE DRAWN AND URINE COLLECTED.

4. AT SELECTED ANNUAL VISITS, I WILL BE GIVEN AN ECG (ELECTROCARDIOGRAM) WHILE I AM RESTING.

5. I WILL BE GIVEN THE SAME SERIES OF PSYCHOLOGICAL TESTS I RECEIVED IN BASELINE VISIT 2.

THE ANNUAL EXAM SHOULD TAKE ABOUT 3 HOURS TO COMPLETE.

I UNDERSTAND THAT THIS AND ALL INFORMATION OBTAINED AS PART OF THE SYSTOLIC HYPERTENSION IN THE ELDERLY PROGRAM WILL BE CONSIDERED CONFIDENTIAL AND ONLY USED FOR RESEARCH PURPOSES. MY IDENTITY WILL BE KEPT CONFIDENTIAL WITHIN THE LIMITS OF THE LAW.

Participant's Initials _____

FOR THIS STUDY TO BE A SUCCESS, IT IS IMPORTANT THAT I REMAIN IN COMMUNICATION WITH THE STUDY AND IF I LOSE TOUCH WITH THE CLINIC, THEY WILL TRY TO FIND ME TO ASK ABOUT MY HEALTH. FOR THIS REASON, I AGREE TO TELL THE CLINIC WHEN I MOVE AND ALSO TO PROVIDE NAMES, ADDRESSES AND PHONE NUMBERS OF RELATIVES WHO WILL KNOW MY STATE OF HEALTH.

I UNDERSTAND THAT MY SOCIAL SECURITY OR MEDICARE NUMBER WILL BE USED TO HELP THE SHEP CLINIC KNOW IF I AM IN THE HOSPITAL. I ALSO UNDERSTAND THAT THIS IS NO WAY WILL AFFECT MY MEDICARE COVERAGE.

I AGREE TO TRY MY BEST TO KEEP APPOINTMENTS AT THE CLINIC AND TO LET THE CLINIC KNOW IF I NEED TO CHANGE APPOINTMENTS OR WHEN I HAVE ANY PROBLEMS FOLLOWING THE INSTRUCTION OF THE CLINIC STAFF.

I UNDERSTAND THAT _____ HAS MADE NO PROVISIONS FOR MONETARY COMPENSATION TO ME IN THE EVENT OF PHYSICAL INJURY RESULTING FROM THE RESEARCH PROCEDURES. SHOULD PHYSICAL INJURY OCCUR, MEDICAL TREATMENT IS AVAILABLE, BUT TREATMENT IS NOT PROVIDED FREE OF CHARGE.

MY PARTICIPATION IN THE STUDY IS ENTIRELY VOLUNTARY AND WILL NOT AFFECT ANY MEDICAL CARE TO WHICH I AM ENTITLED. I ALSO UNDERSTAND THAT TREATMENT FOR MY ISOLATED SYSTOLIC HYPERTENSION IS AVAILABLE FROM MY OWN USUAL SOURCE OF CARE, IF I DECIDE NOT TO PARTICIPATE IN THIS STUDY. FURTHER, I AM FREE TO REFUSE TO TAKE PART OR WITHDRAW AT ANY TIME. I HAVE BEEN GIVEN A COPY OF THIS FORM.

_____ HAS DISCUSSED THIS INFORMATION WITH ME AND IF I HAVE ANY QUESTIONS ABOUT THE STUDY, I CAN CALL _____.
(TELEPHONE NUMBER)

SIGNATURE: _____

WITNESS: _____

DATE: _____