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INFORMED CONSENT FORM Pharmacy Based Activities to Reverse and Manage Disease (PhARMD): The Hypertension Project

Funding Source: Community	Pharmacy Foundation
_	IRB approval #

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Institutional Review Board, Office of Grants and Contracts, Nova Southeastern University: (954) 262-5369

Description of the Study: This project asks the question, can a busy neighborhood pharmacy effectively conduct a screening, monitoring, and referral program for hypertension among a minority population? Our idea is that community pharmacies can help people by working to prevent heart attacks and strokes.

A pharmacy employee with special training or NSU faculty member accompanied by NSU pharmacy student will take your blood pressure. You will be asked to sit quietly for 5 minutes in a semi-private area. While you are sitting, we will ask you a few questions about yourself that may identify risk factors for heart disease and stroke. After the questions, we will use an automated blood pressure device with an adult sized arm cuff to take your blood pressure. To check for obesity, you may be asked to step on a scale to gauge your weight and height. The pharmacy employee (or NSU faculty member and NSU pharmacy student) will offer to counsel you about what these measures mean and you will be offered printed information on the warning signs of a heart attack and brain attack (stroke).

Based on the findings of the screening measures, we may:

- 1. Recommend that you return for monitoring monthly of your blood pressure OR get your blood pressure re-checked in one year.
- 2. Refer you to the attention of a physician for a diagnosis or possible change in therapy.
- 3. Offer you an appointment with a clinical pharmacist for cholesterol and/or glucose (blood sugar) testing and counseling on possible actions to take to reduce your health risk. This conversation will be conducted in a semi-private area in the pharmacy where others cannot overhear the discussion.

Costs and Payments to the Participant: There is no cost for participation in this study and you will not receive money for participating. There is no penalty for withdrawal from the study.

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Risks/Benefits to the Participant: We do not anticipate your experiencing any negative effects as a result of your participation in the study. The benefit to you is learning about your health risks at this point in time and referrals if needed to doctors. If you have any concerns about the risks or benefits of participating in this study, you can contact Dr. Harrington or the IRB office at the numbers indicated above.

Confidentiality: Information obtained in this study is strictly confidential, unless disclosure is required by law. The screening and counseling will be conducted in private areas away from the general public. For the purposes of research, you will be assigned a study number, and this number, rather than your name, will be recorded on the various documents kept including the testing results and risk interviews. All information will be secured in a locked filing cabinet in the pharmacy or at the NSU pharmacy school. Your personal information will not be used in the reporting of information in publications or conference presentations. The results of the study will be reported in terms of the various treatment groups, not in terms of individuals. Thus your anonymity and confidentiality will be protected.

Participant's Right to Withdraw from the Study: You may choose not to participate or to stop participation in the research program at any time without penalty. If you choose not to participate, the information collected about you will be destroyed.

Voluntary Consent by Participant: Participation in this research project is totally voluntary, and your consent is required before you can participate in the research program. If significant new information related to this study becomes available and this information may affect your willingness to participate in this study, Dr. Harrington or her colleagues will alert you immediately.

I have read the preceding consent form, or it has been read to me, and I fully understand the contents of this document and voluntarily consent to participate. All of my questions concerning the research have been answered. I hereby agree to participate in this research study. If I have any questions in the future about this study they will be answered by Dr. Harrington or her colleagues. A copy of this form has been given to me.

Participant's Signature:	Date:	
Witness's Signature:	Date:	