

Attachment 4c Informed Consent Form for One-on-One Interviews

You are being asked to take part in a research study. This consent form tells you about the study and what you will be asked to do. You can choose to take part in the study or not. If you choose to take part, please sign this form.

Purpose of the Research

The purpose of the National Ambulatory Medical Care Survey Supplement on Primary Care Policies for Managing Patients with High Blood Pressure, High Cholesterol, or Diabetes (NSPCP) is to provide much needed data on existing policies and systems in primary care physician practices related to chronic disease management for high blood pressure, high cholesterol, and diabetes. These data will provide in-depth information on the existence of evidence-based systems changes, including multidisciplinary team approaches for chronic disease treatment, electronic health records with features appropriate for treating patients with chronic disease (e.g., clinical decision supports), and patient follow-up mechanisms.

Westat Inc., acting as an agent under contract to National Center for Health Statistics (NCHS), is the data collection agent for the study and is testing a draft survey of the NSPCP. It is important that the questions make sense, are easy to answer, and that everyone understands the questions the same way so that appropriate data collection mechanisms can be constructed. Your interview will help us improve the NSPCP questions.

Procedures

An interviewer will ask you to fill out the NSPCP survey in person or on the telephone. Additionally, the interviewer will ask you open-ended questions about your experiences filling out the questionnaire, what certain words mean to you and how you chose your survey answers.

The interview will last no more than 75 minutes, and the interviewer will give you \$150 in appreciation for your assistance. In order to receive the \$150, you will need to fill out a receipt indicating that you received the incentive for record-keeping purposes.

You may choose not to answer any question for any reason. If you do not want to answer a question, say so, and the interviewer will move on to the next one. You may also stop the interview at any time.

If you have questions about how the project works, contact Christine Lucas by phone at (301) 458-4071 or by mail at Centers for Disease Control and Prevention's National Center for Health Statistics, Room 3320, 3311 Toledo Rd., Hyattsville, MD 20782.

Recordings

As our agent, Westat Inc. would like to audio record your interview. The recording allows us to keep a record of what was asked and what was said. At the bottom of this form, you will be asked if you are willing to have the interview recorded. If you agree, you may ask to stop the recording at any time, and the interviewer will turn off the machine. If you decide to stop recording, the interviewer will ask your consent to retain the portion already recorded.

Privacy

The interview will be conducted in a closed office. NCHS is required by law¹ to tell you how the recorded interview will be used and how your privacy will be protected.

Audio recordings are stored in a locked room or secured by a password. All recordings are labeled by a code number, date, time, and project title. The recording is never labeled with your

Attachment 4c Informed Consent Form for One-on-One Interviews

name or other personal facts. At a later time, Westat Inc. cognitive interviewing team and staff from CDC's National Center for Health Statistics who work with the NSPCP may listen to the interview to evaluate the survey question responses. Recordings will be deleted once notes are transcribed and all cognitive interview reports are finalized.

Materials with personal facts (names, addresses, phone numbers, email addresses) are stored on a password-protected computer network accessible only by members of the cognitive interviewing team. The personal facts will be stored for the duration of the cognitive interviewing period plus three years to ensure that the team has access to it should the need arise. NCHS or its agent may use your personal facts to re-contact you to clarify your answers to the NSPCP, but will not use the information for any other purpose.

Your name or other personal facts that would identify you will not be used in written reports or discussions of this study. NCHS staff and Westat Inc. agents working on this project, however, may recognize your voice.

Your individual responses will not be shared with other physicians or anyone other than NCHS staff and Westat Inc. agents working on this project. Only summary reports will be available to those interested in the results of the NSPCP.

If you have questions about the Centers for Disease Control and Prevention's National Center for Health Statistics privacy laws and practices, contact Eve Powell-Griner, Confidentiality Officer at 1-888-642-4159.

Benefits and Risks

Other than the \$150 you receive, there are no direct benefits from taking part in this study.

The possible risks of taking part in this study are minimal. You do not have to give us any information that you do not want to, and you can choose not to answer any question in the interview. You may also stop at any time and still receive the full \$150. If you have any questions about this study, please call the office of the Ethics Review Board at the Centers for Disease Control and Prevention's National Center for Health Statistics, toll-free at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol #XXX. Your call will be returned as soon as possible.

Please Read and Sign Below if You Agree

- I freely choose to take part in this research study.
- I allow Westat Inc. to audio record my interview for use by NCHS and Westat staff working on this project.
- I do not allow Westat Inc. to audio record my interview.

Participant Signature

Print Name

Date

Attachment 4c Informed Consent Form for One-on-One Interviews

¹The Public Health Service Act provides NCHS with the authority to do this research (42 United States Code 242k). All information which would permit identification of any individual, a practice, or an establishment will be held confidential, will be used only by NCHS staff, contractors, and agents only when required and with necessary controls, and will not be disclosed or released to other persons without the consent of the individual or the establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act (PL-107-347).