Attachment P: Informed Consent Form
Demonstration of Health Literacy Universal Precautions Toolkit
Consent for Participation in a Research Study

Project Title:	*Demonstration of Health Literacy Universal Precautions Toolkit*
Project Funder:	Agency for Healthcare Research and Quality (AHRQ)
Principal and Co-Investigators:	**David West, PhD** Project Director Colorado Health Outcomes Program, University of Colorado Denver **Angela Brega, PhD** Task Order Leader Colorado School of Public Health, University of Colorado Denver
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Invitation to Participate
Your primary care practice/clinic is participating in the Demonstration of Health Literacy Universal Precautions Toolkit. As part of the project, the practice will implement four tools from *Health Literacy Universal Precautions Toolkit*, which is designed to help primary care practices to engage in health literacy-related quality improvement activities, with the goal of improving communication with and support for patients of all literacy levels. We would like to invite you to share your experiences with Toolkit implementation as part of the project. This study is coordinated by the American Academy of Family Physicians (AAFP) National Research Network. It will be performed by study members from your staff and research team members from the AAFP National Research Network and the University of Colorado Denver.

Who will Participate
Twelve primary care practices will participate in this study. Each practice will develop a Health Literacy Team to oversee implementation of the Toolkit. The Health Literacy Team Leader, other members of the Health Literacy Team, and members of the practice staff who are not on the Health Literacy Team will share their experiences with Toolkit implementation with the project team.

Purpose
The project will document how the *Health Literacy Universal Precautions Toolkit* assists primary care practices to implement selected components of the Toolkit and will measure what changes these practices make as a result of Toolkit implementation during the study period. The project team will use study findings and input from practice staff to develop a revised version of the Toolkit.

Procedures
Practices selected to participate will have a six-month implementation period, during which time each practice will implement at least four tools from the Toolkit. During the month before and the month after implementation, practice staff will collect pre- and post-implementation data. At the pre- and post-implementation time points, members of the research team will conduct site visits to each participating practice, during which interviews with selected members of the practice staff will take place.

If you serve as your practice's Health Literacy Team Leader, you will be asked to do the following:

- Complete the Health Literacy Team Leader Survey at both pre- and post-implementation to provide information about your practice's health literacy-related systems and procedures. Completion of the survey should take you no longer than 15 to 20 minutes at each time point.
- Participate in in-person interviews at your practice during the pre- and post-implementation site visits. The interview

conducted at the pre-implementation site visit will focus on your expectations regarding Toolkit implementation and technical assistance needs, and should take no longer than 30 minutes. At the post-implementation time point, the interview will focus on Toolkit implementation and suggested refinements to the Toolkit, and should take about 90 minutes of your time.

- Talk with members of the research team by telephone on four occasions during the implementation period to discuss progress on Toolkit implementation and address any challenges you may be facing. Each call will last 30 minutes. You will be asked to complete or update an Implementation Tracking Form at the beginning of the project period, before each check-in call, and at the end of the implementation period. This form will take approximately five minutes to complete.

If you are a member of the Health Literacy Team, but not the Team Leader, you will be asked to participate in a single interview at the post-implementation site visit. The interview will focus on your perceptions regarding Toolkit implementation and suggestions for refining the Toolkit, and should take up to 90 minutes of your time.

If you are not a member of the Health Literacy Team, you will be asked to participate in one interview at the post-implementation site visit. The interview will focus on your perceptions regarding Toolkit implementation and will take 30 minutes of your time.

All survey and interview data will be kept confidential to the extent permitted by law. No one other than the members of the research team will have access to the answers provided by practice staff. All on-site and telephone interviews will be audio-recorded by a member of the research team and later transcribed for data analysis. Names will not be included in the transcriptions.

Voluntary Participation
Participation in this study is voluntary. You may choose to not participate or to withdraw your participation at any time. Deciding not to participate or choosing to leave the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to leave the study, the information you have already provided will remain a part of the research study.

Fees and Expenses
There are no monetary costs to you as a participant in this research study.

Payments for Participation
Participating practices will be paid a total of $3,000 as vendors to compensate them for time spent on this project. This is a practice-level intervention and you will receive no direct personal compensation for your participation in this study.

Risks and Inconveniences
There are no known or anticipated risks from this study. The surveys and interviews developed for this project, as well as other data collection materials, involve no sensitive questions. There may be a risk of minor inconvenience related to devoting staff time to implementing these components of the project. The project staff will work diligently to ensure that all data remain confidential.

Benefits
Implementing tools designed to improve communication with and support for patients may result in improved delivery of care, greater satisfaction in clinician-patient encounters, and improved patient understanding of their medical conditions and treatment regimens, possibly leading to enhanced patient outcomes. There are also potential direct benefits for practices participating in this project:

- Opportunity to share thoughts and feedback about the Toolkit and its implementation in a primary care setting that will inform a revised version of the Toolkit.
- Opportunity to learn more about health literacy issues in healthcare and to assess their practice's operations/communications from a health literacy perspective.
- Opportunity to contribute to the knowledge of the discipline and science of family medicine and health literacy in the primary care setting.

Alternatives to Study Participation
The alternative is to not participate in this study.

Confidentiality
While every effort will be made to keep confidential all of the information you complete and share, it cannot be absolutely guaranteed. Individuals from the American Academy of Family Physician's Institutional Review Board (a committee that reviews and approves research studies) and Federal regulatory agencies may look at records related to this study for quality improvement and regulatory functions.

Research staff will keep all identifying information confidential to the extent permitted by law. Participating practice staff may opt to not answer any question or may discontinue the survey/interview at any point in time. No practice-level data will be identified outside of the research team unless explicit permission is granted in advance by the practice. The results of this study may be published for scientific purposes or presented at research forums. However, you will not be identified in such circumstances—your information will be combined with the information of others and the combined results will be reported.

Questions

If you have any questions about the study that you are participating in, you are encouraged to contact Liz Horsley (project manager) at 1-800-274-2237 extension 3173 or ehorsley@aafp.org. If you have any questions about your rights as a research subject, you are encouraged to contact Mindy Cleary, AAFP IRB Assistant, at 913-906-6000 extension 6452 or mcleary@aafp.org.

Signing this document means that you have read the information provided in this Informed Consent Form and have had your questions answered to your satisfaction, and voluntarily agree to participate in this study. This consent or a copy of this consent will be kept at AAFP Headquarters in Leawood, Kansas. Please keep a copy of this consent form for your records.

Your Printed Name: _____

Signature _____ Date: _____

Printed Name of Person Explaining Project: _____

Signature _____ Date: _____