Consent to Participate in Research

Title of Research:

Technical Assistance for Health IT and Health Information Exchange in Medicaid and SCHIP

Introduction

You are being asked to participate in a research study. Before you decide if you want to take part in this study, you will need to read this Informed Consent form so that you understand what the study is about and what you will be asked to do. This form also tells you who can be in the study, the risks and benefits of participating in the study, how we will protect your information, and who you can call if you have questions. Please ask the interviewer to explain anything you don't understand before you make your decision.

Purpose

Technical Assistance for Health IT and Health Information Exchange in Medicaid and SCHIP is a 3-year project sponsored by the Agency for Healthcare Research and Quality (AHRQ). The project is being conducted by RTI International, a research organization located in Research Triangle Park, North Carolina. The purpose is to provide technical assistance (TA) to Medicaid and SCHIP agencies surrounding the implementation of health IT and Health Information Exchange (HIE). Medicaid and SCHIP agencies from all 56 states and territories will be invited to participate in the project.

Procedures

Upon your agreement to participate, in Year 1 of the project, RTI will conduct an interview with you or the designated person(s) to assess your agency's needs in implementation of health IT and Health Information Exchange. The interview will either be conducted by teleconference/webex or in-person at your agency, or both. The interviewer will ask both closed and open ended questions. Your responses will then be entered into an electronic database, housed securely at RTI. When scheduling a site visit, RTI will review the agenda with the director (or his/her designate) to determine the personnel best able to provide information on key topic areas (e.g. characteristics of the population served, data capture systems, presence of ongoing health IT/HIE initiatives, business functions, etc.) and schedule meetings with each staff member and key stakeholders.

In Year 2, RTI will approach your agency again to schedule a re-assessment of the TA needs of your agency and evaluate the TA provided so far. RTI will revise the TA program to incorporate the

feedback from the results of the re-assessment and evaluation. Evaluation will be repeated in Year 3 to further improve TA. No re-assessment will occur in Year 3.

Study Duration

This is a three-year project. Your participation in the Needs Assessment interview in Year 1 will take approximately 2 to 2 ½ hours. Review of materials and responses may require the input of more than one person at the agency and we have estimated that overall agency participation in the needs assessment will take no longer than 4 hours and 10 minutes. In Year 2, we will approach your agency again for a re-assessment of your agency's TA needs.

Evaluation instruments will be distributed immediately following any special TA modules such as webinars or group TA workshops. These evaluations will not take more than 25 to 30 minutes each to complete. The results of these evaluations will be used by AHRQ to improve TA provision.

Possible Risks or Discomforts

Risks from the interview:

If the interview involves more than one person from the Agency, then there could be some risk of disciplinary action for those who speak out about the state's political environment or barriers to health information technology. To minimize this risk, we ask that everyone in the group interview hold all of the information discussed confidential and not share any information with others outside of the group being interviewed. In addition, RTI International will take appropriate steps to ensure the confidentiality of the information provided during the interviews.

If any additional, unforeseen problems arise, you should report these to the interviewer immediately. Every effort will be made by the project team at RTI to address any such problems.

Benefits

Your Benefits

You do not need to participate in the Needs Assessment to participate in the TA program. By participating in this program, your agency will receive various forms of assistance that are expected to improve the day-to-day implementation of your health IT and HIE operations.
These direct services include:

- Direct TA in areas of identified need
- Access to a bank of resources and tools intended to facilitate streamlined and effective health IT and HIE systems

- Access to a Help Desk, toll-free number, and email address to assist in accessing these resources

In addition, you will be invited to join a forum of states and agencies to discuss mutual challenges and strategies for implementing health IT and HIE. This and other group platforms to be established and provided through this project, will provide linkage to other states and agencies which will likely enable long-lasting partnerships and collaborations to develop.

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Benefits for Other People

Medicaid has been incrementally expanded to become a primary source of healthcare for a much larger population of medically vulnerable individuals, including poor families, the disabled and persons with developmental disabilities who require long term care. Owing to certain characteristics of Medicaid and SCHIP beneficiaries, these programs are likely to reap greater benefits from health IT and HIE than the general US population. Real-time, point-of –care information on past encounters, immunizations , test results, and other health related data can help Medicaid/SCHIP providers reduce cost, adverse drug events, and duplicate services, better adhere to practice guidelines, improve the management of chronic conditions and coordinate with other providers serving the same patient. This project aims to offer Technical Assistance related to health Information Technology and Health Information Exchanges to Medicaid and SCHIP agencies in all 56 states and territories which will help them improve quality of service and reduce cost thereby benefiting millions of beneficiaries.

Alternatives to Participation in this Research

Your participation in this project is completely voluntary. However, once you agree to participate, we hope you will remain in the project till the end of the project's three-year term.

If you choose not to participate, you will still have access to publicly available resources for health IT and HIE, such as those listed on the Resources document mailed in this packet. If you feel your agency is not ready to participate in Year 1, you will be invited again in Year 2.

Confidentiality

Many precautions have been taken to protect your information. Your name, title, and organizational affiliation will be replaced with a number. If the results of this study are presented at scientific meetings or published in scientific journals, no information will be included that could identify you or your answers personally. In addition, all RTI personnel who are in direct contact with agencies or have access to identifiable data will be required to sign confidentiality agreements.

As mentioned under Possible Risks there is a possibility of risk to the careers of agency staff who may speak out about the state's political environment or barriers to the work. It is very important that information shared during these group interviews not be discussed with others. Every step will be taken to ensure your confidentiality.

First, only RTI staff with a business need for access to the data collected through this project will be allowed access. These staff will be required to sign data confidentiality agreements. Second, all RTI computers have PointSec security software, are password protected, and access to shared drives will limited to staff who have signed data confidentiality agreements. Third, when any information is collected in paper form, this will be stored in a locked file cabinet, with only those staff working with the data having access to the file cabinet. Any paper-based data will be expediently entered into an electronic spreadsheet, stored in a password- or right-protected location on the local and/or shared drives, and the paper files shredded.

Information from this study may be given to persons or companies who are contracted by RTI or the sponsor to have access to the research information during and after the study. It is possible that RTI may need to release your name to another party, but this is very unlikely. If this happens, we would release your name but would not release any of your other information.

The Institutional Review Board (IRB) at RTI International has reviewed this project. An IRB is a group of administrators, researchers, and peers who are responsible for assuring that the rights of participants in research are protected. The IRB may review the records of your participation in this research to assure that proper procedures were followed. A representative of the IRB may contact you for information about your experience with this research. This representative will be given your name, but will not be given any of your confidential study data. If you wish, you may refuse to answer any questions this person may ask.

Future Contacts

We may wish to contact you about future studies. If you are contacted in the future, you will be able to make a decision about participating at that time. Your participation in any future studies is completely voluntary.

Your Rights

Your decision to take part in this project is completely voluntary. However, once you decide to participate, you will be expected to remain in the study till the end of the project term. You can refuse any part of the study and you can stop participating at any time. You can refuse to answer any question.

Your Questions

If you have any questions about the study, you may call (*project team member's name and toll-free telephone number)* Linda Dimitropoulos at 312-456-5246…. If you have any questions about your rights as a study participant, you may call RTI's Office of Research Protection at 1-866-214-2043 (a toll-free number).

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

Your signature (or mark) below indicates that you have been read (or have read) the information provided above, have received answers to your questions, and have freely decided to participate in this research. By agreeing to participate in this research, you are not giving up any of your legal rights.

_____ _____

Date Signature (or Mark) of Participant

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Printed Name of Participant

If the participant is unable to read this form, a witness must sign here:
Note: the witness should not be the person who obtains consent.

I was present while this consent document was read to the above research participant. The participant was given an opportunity to ask questions about being in this study and I believe that he/she has agreed to take part in the research.

_____ _____

Date Signature of Witness

_____

Printed Name of Witness

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the above-named individual.

_____ _____

Date Signature of Person Obtaining Consent

_____

Printed Name of Person Obtaining Consent
