



Patient Questionnaire Assessing Perceptions Regarding Point-of-Care Research (POC-R)

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Consent and Authorization Cover Letter

Assessing VHA Patient and Provider Perceptions of Point-of-Care Research

Dear Veteran,

I am writing to invite you to participate in a study of Veterans who get their care at a VA Medical Center. The Veterans Health Administration is interested in understanding patient's perceptions of a new research program called Point-of-Care research. The purpose of this study is to evaluate this program.

I am asking you to fill out a questionnaire. The questionnaire will begin once you have read this cover letter. Answers will be kept secret.

There are no direct benefits for you, but we hope the information from this study will help doctors provide the best clinical care for Veterans. The risks to participating are loss of time and minimal risk of loss of privacy.

If you have questions, complaints, or concerns about this study, or if you think you may have been harmed from being in this study, you can contact the Principal Investigator, Charlene Weir, PhD, from the Salt Lake City VA IDEAS Center at (801) 582-1565, ext. 1913.

Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

It should take 20-30 minutes to complete the questionnaire. Participation in this study is voluntary. You can choose not to take part. You can choose not to finish the questionnaire or omit any question you prefer not to answer without penalty or loss of benefits. By completing this questionnaire, you are giving your consent to participate.

Thank you for considering this opportunity. I appreciate your willingness to participate.

Charlene R. Weir, PhD, RN
Principal Investigator

«Institution»
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«Expiration» «ExpirationDate»
«Number»

The VA is committed to be a "learning healthcare system." Doctors need to be able to track the outcomes of care overall in order to learn what treatments work and what treatments don't work. To solve this problem, the VA has created a new research program, called **Point-of-Care Research**. It is still research, but it happens during regular care.

Here is an example.

Your doctor wants to give you a colonoscopy (a test where they look at your bowels). You have to take a cleansing preparation before you come in. Two types of preparations are used in your clinic. Nobody is quite sure which one is best. So they decide to research the question. The computer randomly assigns you to receive Prep A. That means you had a 50:50 chance of receiving Prep A or Prep B (like a coin toss). You take Prep A. Then you receive the colonoscopy as you normally would. The quality of the preparation is recorded in the medical chart. Your care proceeds normally.

In Point-of-Care Research studies, doctors agree to let the computer decide your treatment choice. They believe that either choice is good. Randomly assigning patients means we can get scientific information.

The VA will use the results from these studies to improve care for a great many veteran patients. This program helps the VA to become an efficient learning healthcare system.

As with all types of VA research, these studies will be reviewed, approved and monitored by the VA's Research Oversight Committees to protect patients' safety, privacy and rights.

Here is a summary of the differences:

1. In regular care, only the doctor decides on the best treatment.
2. In traditional research clinical trials, many more tests are ordered and more follow-up is needed by research physicians than in POC-R studies. The two options being compared are not equal and the impact of the new drug might not even be known yet. The treatment is decided by a computer.
3. In POC-R studies, the doctor and patient both agree that the choice of therapy will be decided by a computer. The 2 options (treatment or therapy) that are being compared are close to being equally effective. No additional lab tests, visits or monitoring are required.

DO YOU HAVE ANY QUESTIONS?

As with all types of VA research, these studies will be reviewed, approved and monitored by the VA's Research Oversight Committees to protect patients' safety, privacy and rights. Patients can withdraw at any time.

Age

Number of times you visited a VA clinic in the past year

- 1-4 times 5-15 times more than 15 times

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Number of times you were in the VA hospital in the past year

The following questions refer to Point-of-Care Research (POC-R). Please take the time to find a pencil and paper. Do you have one now? Now would you please write down the numbers 1, 2, 3, 4, 5, 6 and 7 from left to right in front to remind you of the question format? Please identify the number that best reflects what you believe or think. Remember there are no right or wrong answers.

EXAMPLE: I believe that research is important to improving care.

- 1 Disagree Strongly
- 2
- 3
- 4
- 5
- 6
- 7 Agree Strongly

I'm going to ask you to choose a number between 1 and 7 that best reflects your opinion.

01. I think the POC-R program is a good thing for the VA.

- 1 Disagree Strongly
- 2
- 3
- 4
- 5
- 6
- 7 Agree Strongly

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02. If I was approached to be in a POC-R study for one of my health problems, I would likely participate

- 1 Disagree Strongly
- 2
- 3
- 4
- 5
- 6
- 7 Agree Strongly

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03. If I am randomized by the computer to a treatment, the relationship with my doctor would change a lot:

- 1 Disagree Strongly
- 2
- 3
- 4
- 5
- 6
- 7 Agree Strongly

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04. If I am randomized by the computer to a treatment, the quality of the care I receive would decrease:

- 1 Disagree Strongly
- 2
- 3
- 4
- 5
- 6
- 7 Agree Strongly

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05. If I am randomized by the computer to a treatment, I am worried that my doctor would have less control over my care:

- 1 Disagree Strongly
- 2
- 3
- 4
- 5
- 6
- 7 Agree Strongly

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06. I would be willing to participate in a POC-R study if my provider is in agreement with it:

- 1 Disagree Strongly
- 2
- 3
- 4
- 5
- 6
- 7 Agree Strongly

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07. If I am randomized by the computer to a treatment, I expect I will still receive a full explanation of my care:

- 1 Disagree Strongly
- 2
- 3
- 4
- 5
- 6
- 7 Agree Strongly

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08. If I am randomized by the computer to a treatment, I am contributing to better care for all veterans:

- 1 Disagree Strongly
- 2
- 3
- 4
- 5
- 6
- 7 Agree Strongly

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09. Researchers reviewing my medical chart and extracting data would bother me.

- 1 Disagree Strongly
- 2
- 3
- 4
- 5
- 6
- 7 Agree Strongly

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10. I think the POC-R program will be valuable for the VA.

- 1 Disagree Strongly
- 2
- 3
- 4
- 5
- 6
- 7 Agree Strongly

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11. I believe that the POC-R program will improve the quality of care at the VA.

- 1 Disagree Strongly
- 2
- 3
- 4
- 5
- 6
- 7 Agree Strongly

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12. I think the POC-R program will help all of the veterans.

- 1 Disagree Strongly
- 2
- 3
- 4
- 5
- 6
- 7 Agree Strongly

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13. Participating in clinical research would make me feel like a guinea pig:

- 1 Disagree Strongly
- 2
- 3
- 4
- 5
- 6
- 7 Agree Strongly

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14. Participating in a POC-R study would likely be confusing:

- 1 Disagree Strongly
- 2
- 3
- 4
- 5
- 6
- 7 Agree Strongly

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15. I don't trust the VA to take care of me if I was enrolled in a POC-R study:

- 1 Disagree Strongly
- 2
- 3
- 4
- 5
- 6
- 7 Agree Strongly

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16. I would you be willing to give a blanket (covers all studies) consent yearly to be part of local ongoing POC-R studies.

- 1 Disagree Strongly
- 2
- 3
- 4
- 5
- 6
- 7 Agree Strongly

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These questions are asking about what is important for YOU. For these questions, a number "4" is Neutral.

17. Being informed of the results of a research program is:

- 1 Not very important
- 2
- 3
- 4
- 5
- 6
- 7 Very important

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18. Giving consent at the beginning of every study is:

- 1 Not very important
- 2
- 3
- 4
- 5
- 6
- 7 Very important

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19. My relationship with my doctor is very important to me.

- 1 Not very important
- 2
- 3
- 4
- 5
- 6
- 7 Very important

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20. For you, receiving compensation for participating in research is:

- 1 Not very important
- 2
- 3
- 4
- 5
- 6
- 7 Very important

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21. Keeping your personal health record private is:

- 1 Not very important
- 2
- 3
- 4
- 5
- 6
- 7 Very important

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The following questions will be answered YES or NO:

22. I have been consented to participate in a research study before today (please check).

- Yes
- No

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23. I know other people that have participated in research studies.

- Yes
- No

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