PRIM&R SURVEY

The purpose of this survey is to understand your perspectives on the ethical aspects of activities related to evaluating and improving standard medical practices. These activities include comparative effectiveness research and quality improvement, and may occur in the context of learning health systems. What is common to these activities is that they evaluate practices that fall within a range of what is considered usual clinical care. This is distinct from typical clinical trials that compare new interventions with standard care or with placebos.

Your responses will be used to help inform national policy discussions about the evaluation of the risks of such research and thresholds for informed consent.

The survey includes 31 questions and will take 10-15 minutes to complete. You have been randomly assigned to take one of four versions of this survey, each of which uses different research scenarios. As you answer each question, please respond based on your professional experience reviewing protocols and your knowledge of human subjects regulations.

We appreciate your participation in this voluntary survey. You are free to stop taking the survey at any time. You will be asked to provide contact information at the end of the survey so we can deliver your $20 Amazon certificate. We will separate your contact information from our study data. If you have questions about the study, please contact us at romp@uw.edu. If you have questions about your rights as a research subject, you can call the University of Washington Human Subjects Division at (206)543-0098.

We would like to begin by asking for your views on healthcare and research.

Health systems take different approaches to deciding what treatments to use. For each of the following statements, please indicate your level of agreement.

1. Patient health outcomes are best when clinicians practice according to standardized, evidence-based protocols and pathways.

☐ Strongly disagree ☐ Somewhat disagree ☐ Somewhat agree ☐ Strongly agree

2. Patient health outcomes are best when clinicians have maximum discretion to individualize treatments for their patients.

☐ Strongly disagree ☐ Somewhat disagree ☐ Somewhat agree ☐ Strongly agree

3. Patient health outcomes are best when a health system routinely collects and analyzes clinical data for research purposes.

☐ Strongly disagree ☐ Somewhat disagree ☐ Somewhat agree ☐ Strongly agree

Now we would like to ask for your thoughts on what activities IRBs should review.

4. Which of these characteristics do you believe should <u>always</u> trigger full IRB review?

	Always full IRB review	Not always full IRB review
Using standard clinical pathways to determine patients' treatments	☐	☐
Collecting and analyzing patient data with the intention of improving future practice within a health system	☐	☐
Collecting and analyzing patient data with the intention of testing hypotheses for generalizable knowledge	☐	☐
Collecting and analyzing patient data with the intention of publishing the results	☐	☐
Sharing de-identified patient data with the intention of testing hypotheses for generalizable knowledge	☐	☐
Randomly assigning patients to receive specific treatments	☐	☐
Randomly assigning hospitals or clinics to use specific treatments	☐	☐

Next we would like to ask for your views about informed consent.

5. In your opinion, who may ethically obtain informed consent for a study that randomizes patients to different forms of usual care?

	Yes, may ethically obtain consent	No, should not obtain consent
The patient's clinician	☐	☐
An investigator who is not involved with the patient's care	☐	☐
A research nurse/study coordinator who is not involved with the patient's care	☐	☐

6. In your opinion, please indicate your <u>preference</u> for who should obtain informed consent. (Please rank from most preferred to least preferred. Only one selection is allowed for each column.)

	Most preferred	Less preferred	Least preferred
The patient's clinician	☐	☐	☐
An investigator who is not involved with the patient's care	☐	☐	☐
A research nurse/study coordinator who is not involved with the patient's care	☐	☐	☐

7. In your opinion, is it ever acceptable to waive informed consent for a study that randomizes patients to different forms of usual care?

☐ Never acceptable ☐ Rarely acceptable ☐ Sometimes acceptable ☐ Usually acceptable

>>if Rarely acceptable or sometimes acceptable selected, GO to 7a

7a. In your opinion, would it be more acceptable to waive informed consent for such a study <u>if all arms are minimal risk</u>?

☐ Yes, more acceptable ☐ No, no change

8. In your opinion, is it ever acceptable to waive informed consent for a study that randomizes hospitals or clinics to different forms of usual care?

☐ Never acceptable ☐ Rarely acceptable ☐ Sometimes acceptable ☐ Usually acceptable

9. Please share your thoughts on any of these issues regarding informed consent. [text box]

Now we would like you to focus on issues concerning patient trust. <u>To maintain patient trust</u>, how important are the following items?

10. Clinicians allow patients to participate in the decisions about the treatments they receive.

☐ Not at all important ☐ Somewhat important ☐ Moderately important ☐ Very important

11. Clinicians assure patients that they are providing the treatments that are best for them.

☐ Not at all important ☐ Somewhat important ☐ Moderately important ☐ Very important

12. Clinicians acknowledge to patients when there is uncertainty regarding which treatment is best for a patient's condition.

☐ Not at all important ☐ Somewhat important ☐ Moderately important ☐ Very important

13. The health system assures patients that their clinical information will be kept confidential.

☐ Not at all important ☐ Somewhat important ☐ Moderately important ☐ Very important

14. The health system includes a community or patient advisory board in overseeing research activities.

☐ Not at all important ☐ Somewhat important ☐ Moderately important ☐ Very important

Scenario: Medical Record Review

Now we would like you to consider a specific context (hypertension (atrial fibrillation)) related to evaluating and improving usual medical practices:

A health system will compare the relative effectiveness of two commonly used FDA-approved drugs (Drug A and Drug B) meant to treat hypertension (anticoagulation to treat atrial fibrillation).

- Data are lacking on the relative effectiveness of Drug A and Drug B in reducing the incidence of heart disease (stroke).
- Drug A and B both cause mild side effects that are similar in frequency.

The health system wants to systematically collect data on heart disease (death from stroke) and other outcomes among patients age 55 (75) and older who are newly diagnosed with hypertension (atrial fibrillation).

- Out-of-pocket cost to patients is the same for either treatment.
- No additional blood or clinical information will be collected beyond what is needed for clinical care.
- The health system intends to base future practice on its analysis of these data and to publish the results so others may use these data.

In this health system,

- **Clinicians decide** to use either Drug A or Drug B for newly diagnosed patients based on their own judgment and patient needs.
- A retrospective review of medical records will be conducted after 4 years.

15. In your opinion, what do you believe is the <u>minimum acceptable</u> approach to patient notification or permission for this scenario? (Please choose only one.)

☐ **No notification.**

☐ **Health system gives each patient a document containing general information.**

☐ **Clinicians or other personnel discuss the health system's plan with patients with hypertension (atrial fibrillation), who are then asked for <u>verbal permission</u>.**

☐ **Clinicians or other personnel discuss the health system's plan with patients with hypertension (atrial fibrillation), who are then asked for <u>written permission or consent</u>.**

>>if selected, GO to 15a:

15a. In your opinion, what do you believe is the <u>minimum</u> material that should be provided as part of getting written permission? (Please choose only one.)

☐ **Patients receive a single-page document that highlights only the elements of informed consent that are most relevant to the patients' potential participation in this activity.**

☐ **Patients receive a multipage document that relays all the elements of informed consent.**

16. In your opinion, what do you believe is the preferred approach to patient notification or permission for the hypertension (atrial fibrillation) scenario? (Please choose only one.)

☐ **No notification.**

☐ **Health system gives each patient a document containing general information.**

☐ **Clinicians or other personnel discuss the health system's plan with patients with hypertension (atrial fibrillation), who are then asked for verbal permission.**

☐ **Clinicians or other personnel discuss the health system's plan with patients with hypertension (atrial fibrillation), who are then asked for written permission or consent.**

The Common Rule directs IRBs to "consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research)."

Please consider the range of risks that patients might encounter in the hypertension (atrial fibrillation) scenario just presented and indicate which of the following is a risk from usual care, a risk from the research, or both. (you may choose more than one answer)

	Usual care	Research
17. Risk of heart disease (stroke) from hypertension (atrial fibrillation)	☐	☐
18. Risk that Drug A is better than Drug B, or vice versa	☐	☐
19. Risk to privacy from the use of clinical data	☐	☐

>>if research to any of the above, GO to follow-up questions including only "research" answers

What level of research risk does this involve?

	Minimal risk	More than minimal risk
17a. Risk of heart disease (stroke) from hypertension (atrial fibrillation)	☐	☐
18a. Risk that Drug A is better than Drug B, or vice versa	☐	☐
19a. Risk to privacy from the use of clinical data	☐	☐

To what extent do you believe prior patient awareness of this medical records review scenario would affect patients' trust…

20. …in their clinicians?

☐ Greatly decrease trust ☐ Decrease trust ☐ No effect ☐ Increase trust ☐ Greatly increase trust

21. …in their health system?

☐ Greatly decrease trust ☐ Decrease trust ☐ No effect ☐ Increase trust ☐ Greatly increase trust

Scenario: Randomization

Now we would like you to consider a different scenario in the same context (hypertension (atrial fibrillation)) to evaluate and improve usual medical practices.

In this health system,

- All newly diagnosed patients are **randomly assigned** to receive either Drug A or Drug B.
- Patients and their doctors know which drug the patient has received (i.e., no blinding).
- Clinicians provide usual medical follow-up and do not change the medication unless a patient experiences an adverse effect or a failure to respond clinically that meets predetermined criteria or the patient requests a change.
- An ongoing review of medical records will be conducted over 4 years.

The context (hypertension (atrial fibrillation)) remains the same (restated below):

A health system will compare the relative effectiveness of two commonly used FDA-approved drugs (Drug A and Drug B) meant to treat hypertension (anticoagulation in adults with atrial fibrillation).

- Data are lacking on the relative effectiveness of Drug A and Drug B in reducing the incidence of heart disease (stroke).
- Drug A and B both cause serious side effects that are similar in frequency.

The health system wants to systematically collect data heart disease (death from stroke) and other outcomes among patients age 55 (75) and older who are newly diagnosed with hypertension (atrial fibrillation).

- Out-of-pocket cost to patients is the same for either treatment.
- No additional blood or clinical information will be collected beyond what is needed for clinical care.
- The health system intends to base future practice on its analysis of these data and to publish the results so others may use these data.

22. In your opinion, what do you believe is the <u>minimum</u> acceptable approach to patient notification or permission for this scenario? (Please choose only one.)

☐ **No notification.**

☐ **Health system gives each patient a document containing general information.**

☐ **Clinicians or other personnel discuss the health system's plan with patients with hypertension (atrial fibrillation), who are then asked for <u>verbal permission</u>.**

☐ **Clinicians or other personnel discuss the health system's plan with patients with hypertension (atrial fibrillation), who are then asked for <u>written permission or consent</u>.**

>>if selected, GO to 22a:

22a. In your opinion, what do you believe is the <u>minimum</u> material that should be provided as part of getting written permission? (Please choose only one.)

☐ **Patients receive a single-page document that highlights only the elements of informed consent that are most relevant to the patients' potential participation in this activity.**

☐ **Patients receive a multipage document that relays all the elements of informed consent.**

23. In your opinion, what do you believe is the <u>preferred</u> approach to patient notification or permission for this scenario? (Please choose only one.)

☐ **No notification.**

☐ **Health system gives each patient a document containing general information.**

☐ **Clinicians or other personnel discuss the health system's plan with patients with hypertension (atrial fibrillation), who are then asked for verbal permission.**

☐ **Clinicians or other personnel discuss the health system's plan with patients with hypertension (atrial fibrillation), who are then asked for written permission or consent.**

The Common Rule directs IRBs to "consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research)."

Please consider the range of risks that patients might encounter in the randomization scenario just presented and indicate which of the following is a <u>risk from usual care, from the research, or both</u>. (you may choose more than one answer)

	Usual care	Research
24. Risk of heart disease from hypertension (atrial fibrillation)	☐	☐
25. Risk that Drug A is better than Drug B, or vice versa	☐	☐
26. Risk of randomization to assign the patient's drug	☐	☐

>>if research to any of the above, GO to a follow-up question including only "research" answers

What level of research risk does this involve?

	Minimal risk	More than minimal risk
24a. Risk of heart disease (stroke) from hypertension (atrial fibrillation)	☐	☐
25a. Risk that Drug A is better than Drug B, or vice versa	☐	☐
26a. Risk of randomization to assign the patient's drug	☐	☐

To what extent do you believe prior patient awareness of this randomization scenario would affect patients' trust…

27. ... in their clinicians?

☐ Greatly decrease trust ☐ Decrease trust ☐ No effect ☐ Increase trust ☐ Greatly trust increase

28. … in their health system?

☐ Greatly decrease trust ☐ Decrease trust ☐ No effect ☐ Increase trust ☐ Greatly increase trust

Finally, please tell us a little bit about yourself.

29. Have you had experience as any of the following? (Please select all that apply.)

☐ Clinician (nurse, psychologist, physician) >>if selected, GO to 29a
☐ Researcher >>if selected, GO to 29b
☐ IRB staff, member, or chair >>if selected, GO to 29c

29a. What is/was your clinical focus? (Please select all that apply.)

☐ Pediatric
☐ Adult

29b. What is/was your research focus? (Please select all that apply.)

☐ Laboratory research
☐ Clinical research
☐ Health services/outcomes research
☐ Psychological, behavioral, or social sciences research
☐ Other

29c. What is/was your IRB role? (Please select all that apply.)

☐ IRB chair/vice chair
☐ IRB member
☐ IRB staff

Would you tell us about your personal experiences as a healthcare user?

30. Have you…

	Yes	No
…seen a health care provider in the last 12 months?	☐	☐
…stayed in the hospital for at least one night in the last 12 months?	☐	☐

31. Do you have any final thoughts you would like to share? [text box]

Thank you for participating in this survey. Your responses are valuable, and we appreciate you sharing your time and expertise.

The results of this survey may lead to additional questions about how those in the field of human subjects protections view research within the standard of care. We would like to interview survey participants to address these questions. Interviews will be approximately 45-minutes and will take place 2-6 months after the survey. Please provide your contact information if you are willing to be contacted.

First Name:
Last Name:
Email address:
Phone number:

END PAGE

Final Page Text

Thank you for participating in the "Attitudes about the Ethics of Research on Medical Practices (RoMP)" survey.

For more information about our project, please visit our website at www.rompethics.org