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*Title:* A Comparison of IRB and Patient Views on Consent for Research on Medical Practices

*Short Title:* IRB and Patient Views on Consent

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## ABSTRACT

*Background/Aims:* In the context of research on medical practices, which includes comparative effectiveness research and pragmatic clinical trials, empirical studies have begun to raise questions about the extent to which institutional review boards' (IRBs) interpretations and applications of research regulations align with patients' values. To better understand the similarities and differences between these stakeholder groups, we compare and contrast two surveys: one of IRB members and one of patients, which examine views on consent for research on medical practices.

*Methods:* We conducted online surveys of two target populations between July 2014 and March 2015. We surveyed 601 human subjects research professionals out of 1500 randomly selected from the Public Responsibility in Medicine and Research (PRIM&R) membership list (40.1% response rate), limiting analysis to the 537 respondents who reported having had IRB experience. We also surveyed 120 adult patients out of 225 approached at subspecialty clinics in Spokane, Washington (53.3% response rate). Our survey questions probed attitudes about consent in the context of research on medical practices using medical record review and randomization. The patient survey included three embedded animated videos to explain these concepts.

*Results:* A majority of IRB members distinguished between consent preferences for medical record review and randomization; ranked clinicians as the least preferred person to obtain participant consent (54.6%); and viewed written or verbal permission as the minimum acceptable consent approach for research on medical practices using randomization (87.3%). In contrast, most patients had similar consent preferences for research on medical practices using randomization and medical record review; most preferred to have consent conversations with their doctors rather than with researchers for studies using randomization (72.6%) and medical record review (67.0%); and only a few preferred to see research involving randomization (16.8%) or medical record review (13.8%) not take place if obtaining written or verbal permission would make the research too difficult to conduct. Limitations of our post hoc analysis include differences in framing, structure, and language between the two surveys and possible response bias.

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*Conclusions:* Our findings highlight a need to identify appropriate ways to integrate patient preferences into prevailing regulatory interpretations as IRBs increasingly apply research regulations in the context of research on medical practices. Dialogue between IRBs and research participants will be an important part of this process.

**KEY WORDS:** research on medical practices; comparative effectiveness research; pragmatic trials; research ethics; informed consent

## **A Comparison of IRB and Patient Views on Consent for Research on Medical Practices**

### INTRODUCTION

The increasingly common use of randomization to compare usual medical practices and procedures—including comparative effectiveness research and pragmatic clinical trials, which we collectively term research on medical practices (ROMP)—has raised questions about how to regulate this kind of research. Amidst controversy about how to evaluate risk and develop appropriate consent practices for ROMP [1–5], the Office for Human Research Protections released draft guidance for ROMP’s regulation in late 2014 [6]. The draft guidance, however, has faced significant criticism [7–9] and has yet to be finalized, leaving the task of interpretation and application of research regulations to local institutional review boards (IRBs). In addition, concerns have been raised that some ROMP studies may also fall under Food and Drug Administration (FDA) jurisdiction, leaving IRBs to interpret both whether FDA regulations apply and, if so, what consent approaches they permit [10–11]. In the absence of clear guidelines, IRB professionals have expressed uncertainty about where ROMP should fit within the existing regulatory scheme [12].

At the same time, empirical studies have begun to suggest widespread public support for ROMP [13–14]. Some of these data have raised questions about how closely prevailing regulatory interpretations align with the values of research participants [15]. To the extent that they do not, this may indicate a need for further dialogue between research participants and those who are charged with their protection. Identifying the consilience and divergence between these two groups is therefore a crucial step toward understanding and resolving sources of disagreement.

To better understand IRB and research participant attitudes about ROMP, we surveyed each of these stakeholder groups. We assessed the IRB perspective by surveying members of Public Responsibility in Medicine and Research (PRIM&R), the professional organization for IRB affiliates and other human subjects research professionals. We assessed attitudes of potential research participants by surveying patients in subspecialty clinics. By targeting patients who are actively involved in the health care system,

we sought to expand on previous studies of the general public [13–14] and learn from individuals whose experiences are particularly relevant to questions about patient engagement in research at the point of care. Qualitative studies have started to address IRB [12,16] and patient [17] attitudes about ROMP; our two surveys take the next step of providing a comparison of IRB and patient views on consent practices. Although the differences between our surveys somewhat limit our comparison, the contrast between the two groups raises critical issues for further stakeholder engagement.

## METHODS

### *Overview*

We conducted a post hoc analysis of two self-administered, Web-based surveys of PRIM&R members and patients in subspecialty clinics. A distinct survey was used with each sample. Both surveys covered the same general topics: health care and research, patient trust, notification and consent, and risks of research. Major content, format, and question structure differences are described below. Focus groups and cognitive interviews with IRB professionals and patients [12,17], as well as review by content experts in bioethics and medicine, were used to inform and guide development of both surveys. Specific sampling and recruitment methods for each population are described below. We obtained waivers of documentation of informed consent for both surveys. Surveys were approved by the University of Washington, Stanford University, and IRB Spokane Institutional Review Boards.

### *Sampling and recruitment*

The sample frame for the PRIM&R survey was 3200 U.S. PRIM&R members who have self-identified as engaged in human subjects research issues. PRIM&R is an international organization that includes IRB staff and administrators, researchers, and others interested in the protection of human research subjects. We randomly selected 1500 PRIM&R members, in two waves of 750 each, to send email invitations requesting study participation, along with a link to the survey. Non-respondents were emailed a second invitation 7 days after the first invitation. Remaining non-respondents were mailed a reminder 16 days after the second invitation and a final email invitation 3 days later. Individuals who completed the survey were compensated with a \$20 gift card. Data collection occurred from July 2014 to September 2014.

The sample frame for the patient survey was patients who were actively receiving care at subspecialty clinics in a health system in Spokane, Washington. Clinics were selected based upon the clinical teams' willingness to participate; participating clinics specialized in pulmonology, kidney transplant, nephrology, rheumatology, cystic fibrosis, vascular disease, multiple sclerosis, cardiology, oncology, and mechanical heart care. Enrollment criteria, in addition to having visited one of the subspecialty clinics twice within the last 12 months, were being eighteen years of age or older, able to speak and read English, and able to hear. Eligible patients were pre-identified by clinic staff and approached at the time of a clinic visit by clinic staff and study recruiters together, until we reached our target enrollment. All eligible patients who were present when a recruiter was available to speak with them were approached. A total of 225 eligible patients were initially approached; recruiters logged individuals who were approached but declined to participate (n=86) or agreed to participate but did not complete the survey (n=19). Patients who consented to participate were given the option of completing the survey in the clinic on a provided iPad or on their own computer outside of the clinic using the provided link. Participants who opted to take the survey at a later time gave their contact information at the time of consenting in clinic. Non-respondents were sent email reminders every 2 weeks for 6 weeks. Individuals who completed the survey were compensated with a \$20 gift card. Recruitment and data collection occurred between December 2014 and March 2015.

### *Survey design*

Both the PRIM&R and patient surveys included general questions and questions specific to scenarios provided to illustrate examples of ROMP. The general questions probed attitudes toward, and understanding of, ROMP; views on doctors and health systems; and patient trust. The scenario-specific questions were prefaced with a brief description of one of two hypothetical ROMP studies: one using medical record review and one using randomization. See Figure 1 for scenario text and Table 1 for wording of the questions for which we report results. The major differences between the two surveys are explained below.

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To evaluate PRIM&R-respondents' views on consent for different medical conditions, respondents were randomly assigned to one of two condition-specific versions of the scenarios: hypertension or atrial fibrillation. The first scenario in each version described a medical record review study in which approved medications to treat either hypertension or atrial fibrillation were prescribed based on physician judgment and patient needs. The second scenario described a variation on the first scenario in which patients were randomly assigned to one of the medications, with no blinding of the medications and with usual clinical follow-up. After each scenario, questions were posed to assess attitudes about various consent approaches, including who should obtain participant consent.

To provide basic information to patient-respondents, we created three 2-to-3-minute animated narrative whiteboard videos (<https://rompethics.iths.org/video>) with Booster Shot Media (<http://boostershotmedia.com>), a production company specializing in the development of multimedia patient education materials. Prior research on public attitudes has noted the importance of providing background information on unfamiliar topics to enable participants to express an informed opinion [18–19]. The examples presented in the videos involved FDA-approved antihypertensive medications. The three videos explained factors that influence variation in clinical practice [20], medical record review and randomization as they are used in ROMP [21], and approaches to notifying and obtaining consent from patients [22]. After each of the first two videos, respondents answered questions assessing their understanding of the information in the videos and general attitudes toward ROMP. After the third video, we presented respondents with scenarios involving medical record review and randomization to compare antihypertensive medications, followed by questions to evaluate their consent preferences. All patient-respondents received the same version of the scenarios. Further information about the development and specific content of the videos is described in Cho et al. (2015) [13].

### *Measures*

See Table 1.

### *Data analysis*

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We constrained analysis of the PRIM&R survey to respondents who reported experience on an IRB (n=537). We further constrained the comparative analyses of IRB- to patient-respondents about consent preferences to IRB-respondents randomized to the hypertension survey version (n=267) so that scenario-based comparisons were in the context of the same clinical example: hypertension. Descriptive statistics are reported for specific survey items as well as composite measures, described in Table 1. All data management and statistics were performed using SAS© 9.4.

## RESULTS

### *Respondent characteristics (see Table 2)*

The PRIM&R survey had a 40.1% response rate (N=601/1500). Of the 537 (89.4%) of respondents who reported having had IRB experience, 41.7% reported experience as staff only, 38.9% as a member, and 18.8% as a chair or vice-chair. Additionally, 47.5% reported experience as a researcher and 19.4% as a clinician.

The patient survey had a 53.3% response rate (N=120/225). Most patient-respondents were 45 years of age or older, including over a third each between 45 and 65 (36.4%) and over 65 (42.5%), and self-identified as white (86.7%) and non-Hispanic (98.3%). Patient-respondents had a range of educational and income levels, although more than half (58.0%) earned less than \$55,000 annually and a third (33.3%) less than \$30,000 annually. About half (49.2%) said their health status was “good” and a quarter (24.2%) said it was “fair.”

### *Support for ROMP*

The vast majority of respondents to both surveys broadly supported ROMP: 90.8% of IRB-respondents and 99.2% of patient-respondents agreed that health systems should conduct research to find out which standard medical treatments are best.

### *Consent preferences and acceptability*



Respondents' consent preferences highlighted a distinction between how IRB- and patient-respondents perceive different methodological approaches to ROMP. Because IRB professionals have to distinguish between what is minimally required for approval and what they think is best, we asked IRB-respondents about their views on both the "minimum acceptable" and "preferred" approach to notification or permission. It was left to respondents' interpretation as to whether each of these terms referred to the regulations and/or their personal views. For both questions, IRB-respondents tended to distinguish between ROMP using randomization and medical record review, while patient-respondents did not (Figure 2).

When asked to identify the minimally acceptable approach to notification or permission for ROMP using randomization, very few IRB-respondents found no notification (3.4%) or broad notification (9.4%) acceptable, while 87.3% believed a study-specific discussion was required, with either verbal (18.1%) or written (69.2%) permission. In contrast, for medical record review, more IRB-respondents found no notification (37.5%) or broad notification (20.8%) acceptable, and only 41.7% believed a study-specific discussion with verbal (11.0%) or written (30.7%) permission, was required.

When asked about their preferred approach for informed consent, IRB-respondents' answers again differed by study method, but their responses overall shifted more toward written permission (Figure 2, left columns). For ROMP using randomization, very few IRB-respondents selected no notification (1.9%) or broad notification (4.1%), and the vast majority (94.0%) selected a study-specific discussion with either verbal (12.8%) or written (81.2%) permission. For medical record review, more IRB-respondents selected no notification (24.4%) or broad notification (20.7%); about half (54.9%) selected a study-specific discussion with verbal (18.4%) or written (36.5%) permission.

Patient-respondents, on the other hand, preferred a study-specific discussion for both study methods (Figure 2, right columns). For ROMP using randomization, few patient-respondents preferred no notification (5.0%) or broad notification (15.8%), while most (79.2%) preferred a study-specific discussion with verbal (41.7%) or written (37.5%) permission. Likewise, for medical record review, only a few patient-

respondents preferred no notification (6.7%) or broad notification (15.0%), and again, most (78.4%) preferred a study-specific discussion with verbal (29.2%) or written (49.2%) permission.

Nonetheless, when patient-respondents who indicated an initial preference for written or verbal permission were given the choice to forgo their preferred approach if it made the research too difficult to conduct, only 16.8% said they would rather the research not go forward for ROMP using randomization, and 13.8% for medical record review, than require their preferred approach.

### *Obtaining consent*

IRB- and patient-respondents differed in their preferences for who should obtain consent from patients for ROMP. The majority of IRB-respondents preferred that someone other than a patient's clinician—i.e., an investigator or research staff member—obtain consent (64.7%). A majority (54.6%) identified a patient's clinician as the least preferred person to obtain consent. Moreover, only 66.2% of IRB-respondents said it was ethically appropriate for a patient's clinician to obtain consent for ROMP, compared with the higher proportions who said it was ethically appropriate for investigators (86.3%) or research staff (84.6%) to obtain consent.

Most patient-respondents, however, either preferred that their doctor obtain their consent for ROMP using randomization (72.6%) or had no preference between their doctor and a research staff member (16.8%). For medical record review, 67.0% preferred their doctor and 23.4% had no preference.

## DISCUSSION

In light of the medical community's increasing reliance on ROMP [23–24] and the debate surrounding its regulation, it is important to bring a range of stakeholder perspectives to bear on complex questions about oversight [11]. Qualitative studies have begun to explore stakeholder perspectives on ROMP [12,16–17], and we have previously surveyed a sample of 1095 members of the general public using our patient survey instrument [13]. Our IRB and patient survey data expand on these existing findings and highlight

several critical issues about which IRB professionals' and patients' views diverge and invite further stakeholder engagement.

First, IRB professionals distinguished between review of medical record data and research using randomization, considering verbal consent, or even broad or no notification, appropriate for medical record review but overwhelmingly endorsing a written consent requirement for ROMP using randomization. Patients, however, did not draw the same distinction. Their desire for notification and—when possible—written or verbal consent was similar for both study methods. Our previous survey of the general public likewise found similarity in consent preferences for ROMP using randomization and medical record review [13]. Importantly, our surveys did not assess *why* respondents did or did not distinguish between the two methods. Our findings do, however, align with the results of our earlier qualitative work. In those focus group studies, IRB professionals generally viewed observational research as less risky than ROMP using randomization [12], while patients' overarching concerns related to transparency and the preservation of trust within the physician-patient relationship, regardless of the research method [17]. These results are consistent with studies on attitudes toward biobank research showing that patients are less concerned with methodology and regulations and instead prioritize trust and transparency [25–29].

A second difference between IRB professionals and patients was who they thought should obtain informed consent for ROMP. Patients preferred information to come from their doctor, not a researcher. This accords with findings from our prior qualitative study that patients preferred consent discussions to take place within the context of an ongoing physician-patient relationship [17]; from our survey of the general public, most of whom preferred to discuss ROMP with their doctor for studies using both randomization (85.2%) and medical record review (84.5%) [13]; and from other studies of patient attitudes toward ROMP [29]. These preferences, however, challenge the significance of ethical concerns about physicians taking on the sometimes-conflicting roles of clinician and researcher simultaneously [3,31–32]. IRB professionals in our study may have shared these concerns, given that more than half believed physicians were the least preferred people to obtain consent from patients and a substantial minority

believed it is ethically inappropriate for physicians to do so. While our data are not necessarily dispositive, these differences suggest that IRBs, in light of their charge to protect research participants, should at least take patient's perspectives on this issue into account.

Finally, even though most patients had a baseline preference for written informed consent, many were willing to accept broad notification if getting written or verbal consent would make the research too difficult to conduct. The federal regulations would require a waiver of documentation under 45 CFR 117(c), and possibly an alteration of informed consent under 45 CFR 46.116(a), to use this approach. A majority of IRB professionals, however, said written consent was the minimum acceptable approach for ROMP using randomization. This disconnect suggests that IRBs may be reluctant to approve waivers of documentation or alterations of consent even in situations when patients would be willing to accept something other than written consent. Although our surveys did not specify which consent elements would or would not be included in each approach, our findings—in combination with our previously published focus group data [17] and general public survey data [13]—suggest that, in at least some cases, patients are willing to make tradeoffs that include accepting waivers of documentation and/or alterations of consent. Kim and Miller (2016) argue that alterations of consent should be viewed through the lens of patient respect, meaning they should meet legitimate patient expectations, allow for patient choice, and be contextually appropriate [33]. Our findings align with this patient respect framework and suggest that modified consent approaches, such as a simplified consent process within the context of the physician-patient relationship [4], could respect patients' preferences while fitting within the existing regulatory framework. However, a study like our hypothetical example comparing FDA-approved antihypertensive medications could also, under some interpretations, fall under the FDA regulations at 21 CFR 312, thus raising additional hurdles by limiting options for modified consent approaches [10]. If this important field of research is to move forward in a way that aligns with patient preferences, guidance is needed to clarify whether FDA regulations apply to ROMP and, if so, how alterations of consent and/or waivers of documentation for ROMP might fit within the regulatory scheme.

### *Limitations*

Our comparison of these two surveys is limited because, although we developed both surveys using a similar format and addressed the same concepts, our post hoc analysis does not account for differences in survey framing or wording of questions. Many of these differences were intended to help convey complex regulatory concepts to a lay audience in an understandable way, but they nonetheless pose challenges for interpretation. First, we used our videos as educational tools in the patient survey only. Second, the consent questions were not identical and therefore make it difficult to draw conclusions about specific regulatory approaches, most notably in that they do not explicitly distinguish between waiver of documentation and alteration of consent. Moreover, the framing of our questions might have affected respondents' answers. To mitigate this possibility, we conducted cognitive interviews with representatives of the relevant populations prior to administering each survey and revised questions that were overly confusing or leading. In addition, our response rates may signal potential non-response bias, although empirical literature has shown that increasing response rates up to approximately 80% have only a minimal effect on survey data [34–35]. Finally, patient-respondents were drawn from a single health system and most were middle-aged or older, non-Hispanic white, low-income, and with fair-to-good self-reported health status, which limits the representativeness of this sample. However, when viewed alongside the data from our previously published survey of the general public, who were stratified to match U.S. demographics for age and race/ethnicity and whose income and education were higher than the national average [13], our results are largely consistent with those from our national sample.

## CONCLUSION

Our surveys highlight several differences between IRB professionals' and patients' views on consent for ROMP. As ROMP becomes more prevalent, we urge those with regulatory responsibilities to balance traditional regulatory interpretations with the growing body of evidence about research participants' wishes and values. Our data alone cannot conclusively determine how that balance should be achieved, but they do suggest a need for ongoing engagement and dialogue with potential research participants. This dialogue should inform federal regulators as they consider guidance for ROMP moving forward.

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#### DECLARATION OF CONFLICTING INTERESTS

The authors declare that there is no conflict of interest.

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TABLE 1: Measures

PRIM&R Survey	Patient Survey
<b>Support for ROMP</b>	
<p>"Patient health outcomes are best when a health system routinely collects and analyzes clinical data for research purposes."</p> <ul style="list-style-type: none"> <li>• Strongly disagree</li> <li>• Somewhat disagree</li> <li>• Somewhat agree</li> <li>• Strongly agree</li> </ul>	<p>"Please indicate your level of agreement: To find out which standard medical treatments are best, health systems should conduct research."</p> <ul style="list-style-type: none"> <li>• Strongly agree</li> <li>• Somewhat agree</li> <li>• Somewhat disagree</li> <li>• Strongly disagree</li> </ul>
<b>Consent preferences</b>	
<p><i>[following both medical record review and randomization scenarios]</i> "In your opinion, what do you believe is the preferred approach to patient notification or permission for this scenario?"</p> <ul style="list-style-type: none"> <li>• No notification</li> <li>• Health system gives each patient a document containing general information</li> <li>• Clinicians or other personnel discuss the health system's plan with patients with hypertension, who are then asked for verbal permission</li> <li>• Clinicians or other personnel discuss the health system's plan with patients with hypertension, who are then asked for written permission or consent</li> </ul> <p><i>[following both medical record review and randomization scenarios]</i> "In your opinion, what do you believe is the minimum acceptable approach to patient notification or permission for this scenario?"</p> <ul style="list-style-type: none"> <li>• No notification</li> <li>• Health system gives each patient a document containing general information</li> <li>• Clinicians or other personnel discuss the health system's plan with patients with hypertension, who are then asked for verbal permission</li> <li>• Clinicians or other personnel discuss the health system's plan with patients with hypertension, who are then asked for written permission or consent</li> </ul>	<p><i>[following both medical record review and randomization scenarios]</i> "If you were newly diagnosed with high blood pressure and this research using [medical record review/randomization] were happening in your health system, how would you prefer to be notified about this research?"</p> <ul style="list-style-type: none"> <li>• I would not need to be notified about this research</li> <li>• My health system would give me a document containing general information about this research</li> <li>• Doctors or other medical personnel would discuss this research with me and then ask for verbal permission to participate</li> <li>• Doctors or other medical personnel would discuss this research with me and then ask for written permission or consent to participate</li> </ul> <p><i>[if selected written permission as preferred approach]</i> "If getting written permission or consent would make this research using [medical record review]/[randomization] too difficult to carry out, how would you prefer to be notified about this research?"</p> <ul style="list-style-type: none"> <li>• I would not need to be notified about this research</li> <li>• My health system would give me a document containing general information about this research</li> <li>• Doctors or other medical personnel would discuss this research with me and then ask for verbal permission to participate</li> <li>• I would prefer this research not be conducted</li> </ul> <p><i>[if selected verbal permission as preferred approach OR on previous question]</i> "If getting verbal permission would make this research using [medical record review]/[randomization] too</p>

	<p>difficult to carry out, how would you prefer to be notified about this research?"</p> <ul style="list-style-type: none"> <li>• I would not need to be notified about this research</li> <li>• My health system would give me a document containing general information about this research</li> <li>• I would prefer this research using medical record review not be conducted</li> </ul>
<b>Obtaining consent</b>	
<p>"In your opinion, who may ethically obtain informed consent for a study that randomizes patients to different forms of usual care?"</p> <ul style="list-style-type: none"> <li>• The patient's clinician [Yes/No]</li> <li>• An investigator who is not involved with the patient's care [Yes/No]</li> <li>• A research nurse/study coordinator who is not involved with the patient's care [Yes/No]</li> </ul> <p>"In your opinion, please indicate your preference for who should obtain consent. (Please rank from most preferred to least preferred. Only one selection is allowed for each column.)"</p> <ul style="list-style-type: none"> <li>• The patient's clinician [Most preferred/Less preferred/Least preferred]</li> <li>• An investigator who is not involved with the patient's care [Most preferred/Less preferred/Least preferred]</li> <li>• A research nurse/study coordinator who is not involved with the patient's care [Most preferred/Less preferred/Least preferred]</li> </ul>	<p>"Who would you prefer to ask you for your permission or consent to participate in this research using randomization?"</p> <ul style="list-style-type: none"> <li>• My doctor</li> <li>• A researcher or research nurse who is not involved in my care</li> <li>• No preference</li> </ul>

TABLE 2: Characteristics of survey respondents

IRB members (n=537)*	
	n (%)**
Clinicians	104 (19.4)
Pediatrics	45 (8.4)
Adult	82 (15.2)
Researchers	255 (47.5)
Lab	46 (8.6)
Clinical	145 (27.0)
Health Service/Outcomes	60 (11.1)
Psych, Behavioral, Social Sciences	127 (23.6)
IRB role	
Chair/Vice-Chair	101 (18.8)
Member	209 (38.9)
Staff only	224 (41.7)
* Characteristics are reported only for respondents who reported IRB experience	
** Respondents were instructed to select all that apply, so percentages may not sum to 100	
Patients (N=120)	
	n (%)*
Gender (% male)	54 (45.0)
Age	
21-26	5 (4.2)
27-44	19 (16.1)
45-64	43 (36.4)
65+	51 (42.5)
Race	
White	104 (86.7)
Asian	2 (1.7)
African-American	1 (0.8)
Other/multi-racial	13 (10.8)
Ethnicity (% Hispanic)	2 (1.7)
Educational level	
High school or less	39 (33.3)
Some college/associate	42 (35.9)
College graduate	24 (20.5)
Graduate/professional degree	12 (10.3)
Household income	
\$30,000 or less	33 (33.0)
>\$30,000-\$55,000	25 (25.0)
>\$55,000-\$95,000	28 (28.0)
>\$95,000	14 (14.0)
Self-reported health status	
Excellent	1 (0.8)
Very good	20 (16.7)
Good	58 (49.2)
Fair	29 (24.2)
Poor	12 (10.0)
* Percentages may not sum to 100 due to rounding	

FIGURE 1: ROMP hypertension scenarios

<p><b>PRIM&amp;R survey</b></p> <p><b>Medical Record Review</b></p> <p>Now we would like you to consider a specific context (hypertension) related to evaluating and improving usual medical practices:</p> <p>A health system will compare the relative effectiveness of two commonly used FDA-approved drugs (Drug A and Drug B) meant to treat hypertension.</p> <ul style="list-style-type: none"> <li>• Data are lacking on the relative effectiveness of Drug A and Drug B in reducing the incidence of heart disease.</li> <li>• Drug A and B both cause mild side effects that are similar in frequency.</li> </ul> <p>The health system wants to systematically collect data on heart disease and other outcomes among patients age 55 and older who are newly diagnosed with hypertension.</p> <ul style="list-style-type: none"> <li>• Out-of-pocket cost to patients is the same for either treatment.</li> <li>• No additional blood or clinical information will be collected beyond what is needed for clinical care.</li> <li>• 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.</li> </ul> <p>In this health system,</p> <ul style="list-style-type: none"> <li>• <b>Clinicians decide</b> to use either Drug A or Drug B for newly diagnosed patients based on their own judgment and patient needs.</li> <li>• A retrospective review of medical records will be conducted after 4 years.</li> </ul> <p><b>Randomization</b></p> <p><b>Now we would like you to consider a different scenario in the same context (hypertension) to evaluate and improve usual medical practices.</b></p> <p>In this health system,</p> <ul style="list-style-type: none"> <li>• All newly diagnosed patients are <b>randomly assigned</b> to receive either Drug A or Drug B.</li> <li>• Patients and their doctors know which drug the patient has received (i.e., no blinding).</li> <li>• 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.</li> <li>• An ongoing review of medical records will be conducted over 4 years.</li> </ul> <p>The context (hypertension) remains the same (restated below):</p> <p>A health system will compare the relative effectiveness of two commonly used FDA-approved drugs (Drug A and Drug B) meant to treat hypertension.</p> <ul style="list-style-type: none"> <li>• Data are lacking on the relative effectiveness of Drug A and Drug B in reducing the incidence of heart disease.</li> <li>• Drug A and B both cause mild side effects that are similar in frequency.</li> </ul> <p>The health system wants to systematically collect data heart disease and other outcomes among patients age 55 and older who are newly diagnosed with hypertension.</p> <ul style="list-style-type: none"> <li>• Out-of-pocket cost to patients is the same for either treatment.</li> <li>• No additional blood or clinical information will be collected beyond what is needed for clinical care.</li> <li>• 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.</li> </ul>
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## Patient Survey

### Medical Record Review

Now we would like you to think about the videos and imagine your health system using medical record review to compare 3 high blood pressure medications in newly diagnosed patients.

Doctors don't know which of these medications is better at preventing heart disease.

Each doctor decides which medication to use based on his or her judgment and on patient preferences.

Please assume the following when you are answering the following questions:

- These are commonly used, FDA-approved medications.
- Each medication causes occasional mild side effects.
- The out-of-pocket costs to the patient are the same.

### Randomization

Still thinking about the videos, now imagine that your health system is using randomization to compare the 3 blood pressure medications in newly diagnosed patients.

Each patient and their doctor will know which medication the patient is getting.

Their doctor will provide usual medical follow-up and will not change the medication unless the patient or doctor has concerns.

FIGURE 2: Consent preferences by study method

