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Research on Medical Practices: Why Patients Consider Participating and the Investigational Misconception

Table 1.
ROMP Scenarios and Questions

Scenario	*Willingness to participate (Y/N)*	*Open-ended response*
Scenario 1: Medical record review, hypertension, self		
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.	Would you be willing to consider having your medical records reviewed for this research on high blood pressure medications?	n/a
Scenario 2a: Randomization, hypertension, self		
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.	Would you be willing to consider participating in this research using randomization?	Please tell us more about why you would [not] be willing to consider participating in this research using randomization.
Scenario 2b: Randomization, hypertension, family member		
Imagine that you are the medical decision-maker for one of your close family members (such as a child, spouse, or parent) and they are eligible to participate in this research using randomization.	Would you consider giving permission for them to participate?	Please tell us more about the reasons why you would [not] consider giving permission for them to participate.

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Scenario 3a: Randomization, more serious condition, self		
Finally, consider a more serious health condition that increases your risk for stroke. There are 3 commonly used medications that can reduce your risk, but they all have serious side effects. Imagine your health system using randomization to compare these 3 medications in newly diagnosed patients. These are FDA-approved medications, but doctors don't know which of these medications is better.	Would you be willing to consider participating in this research using randomization?	Please tell us more about why you would [not] be willing to consider participating in this research using randomization.
Scenario 3b: Randomization, more serious condition, family member		
Imagine that you are the medical decision-maker for one of your close family members (such as a child, spouse, or parent) and they are eligible to participate in this research using randomization for this more serious condition.	Would you consider giving permission for them to participate?	n/a

Table 2.
Respondent Characteristics

Characteristic	*All survey respondents (n = 1095)*	*Respondents who answered at least one open-ended question (n = 834)*
Sex (% male)	49.0	46.3
Age		
21-26 years	7.9	6.1
27-44 years	37.4	34.0
45-64 years	37.2	39.7
≥ 65 years	17.6	19.3
Race		
white	74.0	75.3
Asian	2.8	2.8
African American	13.1	12.4
other or multiracial	10.1	9.6
Hispanic ethnicity	16.1	14.3
Education		
high school or less	13.9	11.7
some college or associate's degree	30.5	31.6
college graduate	34.4	34.3
graduate or professional school	21.2	22.5
Household income		
≤ $30,000	16.5	14.8
> $30,000-$55,000	23.2	23.4
> $55,000-$95,000	29.5	29.6
> $95,000	30.8	32.2
Self-reported health status		
excellent	18.3	18.0
very good	40.7	42.1
good	29.0	28.1
fair	10.8	10.7
poor	1.3	1.2
Prior clinical research participant	9.2	8.5
Has children	63.2	64.0

Table 3.
Willingness to Consider Participating in ROMP (n = 1095)

Method	*Condition*	*Prospective participant*	*% willing to consider participating*
Medical record review	Hypertension	Self	80.6
Randomization	Hypertension	Self	72.9
Randomization	Hypertension	Family member	74.2
Randomization	More serious condition	Self	67.4
Randomization	More serious condition	Family member	63.1

Table 4.
Reasons for Being Willing or Unwilling to Consider Participating

Respondents who were willing (all questions combined) (n = 1658)

Reason	*n (%)**
Benefit to others	934 (56.3)
Clinical benefit to the participant	317 (19.1)
Safe	159 (9.6)
Drug similarity	156 (9.4)
Trust in a specific physician or institution	130 (7.8)
Favorable view of randomization	127 (7.7)
Ability to switch medications	112 (6.8)
Conditional on transparency and information	68 (4.1)
Conditional on a patient's ability to make an active choice	33 (2.0)
Misconceptions about ROMP	30 (1.8)
No added risk beyond usual care	28 (1.7)
General or institutional trust or mistrust	21 (1.3)
Curiosity	17 (1.0)

Respondents who were unwilling (all questions combined) (n = 505)

Reason	*n (%)**
Unsafe	178 (35.2)
Unfavorable view of experimentation	136 (27.0)
Desire for physician control over treatment decisions	60 (11.9)
Unfavorable view of randomization	37 (7.3)
Conditional on a patient's ability to make an active choice	34 (6.7)
Conditional on transparency and information	34 (6.7)
Misconceptions about ROMP	30 (6.0)
Privacy or confidentiality	24 (4.8)
General or institutional trust or mistrust	21 (4.2)
Doubt in drug similarity	8 (1.6)

*All relevant codes were applied to each response, so percentages do not sum to 100%.

Appendix
Reasons for Being Willing or Unwilling to Participate—Codebook

Code	*Description*
	1. Benefit
1.1 Clinical benefit	Direct clinical benefit to self or other research participant or motivation to receive benefit on own behalf. Must include use of "my" or "me" or "I" or, for family member questions, be specifically about benefit to family member.
1.2 Curiosity	Self-knowledge, understanding, curiosity, knowledge, information, discovery, etc.
1.3 Others, society, general support for research	Altruism or general support for research (e.g., "I support research") or results of research (e.g., "I want to help find the best treatment"). May reference helping family members, patients, the disease group, society, the future; improving treatments; finding the best drug; the word "help"; or help or benefit for "all."
	2. Risk
2.1 Safety	Safety, including both high risk and low or no risk (e.g., "doesn't seem too risky"). Includes mention of or concerns about side effects.
2.2 Ability to switch medications, leave study	Ability, or perceived lack of ability, of self or doctor to switch or control medications or to leave the study.
2.3 No added risk beyond usual care	Additional risk from the study as compared to the general risk of clinical care.
2.4 Drug similarity	Similar or dissimilar effectiveness of all of the drugs in the study.
	3. Trust or relationships
3.1 Physician or specific institution	Trust or mistrust in personal doctor or specific health care institution, belief that physician will manage or filter risk, or other reference to a clinical relationship. Includes wanting doctor to choose treatments for you.
3.2 General or institutional	Trust or mistrust (including extreme mistrust of system) in medical system, pharmaceuticals, researchers, research and development, drugs, results, method, etc.
	4. Privacy or confidentiality
4.1 Privacy, confidentiality	Concerns about release or sharing of medical records, protected health information, data sharing, etc.
	5. Informed consent
5.1 Active patient choice	Importance of patient's having the choice to participate or not participate; personal control in consent process.
5.2 Transparency, information	Needs more information before deciding, wants to know that research is happening, wants to talk to someone else before deciding, etc.
	6. Research
6.1 Randomization	Specific mention of positive or negative aspects of randomization as a methodological approach. May include sound or unsound research method, sample size, reduced bias, dangers of randomization, concerns about study design (must clearly address randomization, either by name or proxy [i.e., "gold standard"]).
6.2 Experimentation	Dislike of being "experimented" on, including mention of being a "guinea pig" or wanting control over health care or medications. Includes desire for personalized medicine as a reason not to participate.
6.3 Misunderstandings	Misunderstandings or confusions about research design or approach, specifically about placebos, testing new treatments, or other clear misunderstandings of ROMP or randomization.
	7. Specific surrogate issues
7.1 Specific family-member issues	Explicit comments about differences when making decisions for a family member.

	8. Specific "more serious" issues
8.1 Specific "more serious" issues	Explicit comments about differences in the context of a more serious condition.
	9. Vague, irrelevant, other
9.1 Vague, irrelevant, other	Answers that are too vague to interpret, are irrelevant, or do not fit in any of the above categories. Apply only if nothing else fits.