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Reframing Recruitment: Evaluating Framing in Authorization for Research Contact Programs

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ABSTRACT

Background: The changing clinical research recruitment landscape involves practical challenges but introduces opportunities. Researchers can now identify large numbers of eligible patients through electronic health record review and can directly contact those who have authorized contact. Applying behavioral science-driven strategies to design and frame communication could affect patients' willingness to authorize contact and their understanding of these programs. The ethical and practical implications of various strategies warrant empirical evaluation.

Methods: We conducted an online survey (n = 1070) using a nationally-representative sample. Participants were asked to imagine being asked for authorization for research contact in clinic. They were randomly assigned to view one of three flyers: #1-neutral text flyer; #2-a positive text flyer; or #3-positive graphics-based flyer. Primary outcomes included likelihood of enrollment and comprehension of the program. Chi-Square tests and regression analyses were used to examine whether those who saw the positive flyers were more likely to enroll and had increased comprehension.

Results: Compared to the neutral flyer, individuals who received the positive text flyer were numerically more likely to enroll, but this was not statistically significant (24.2% v. 19.0%, p = 0.11). Individuals who received the positive graphics flyer were more likely to enroll (28.7% v. 19.0%, p = 0.002). After adjustment, individuals assigned to both novel flyers had increased odds of being likely to enroll (OR = 1.55 95%CI [1.04, 2.31] and OR = 1.95 95%CI [1.31, 2.91]). Flyer type did not affect overall comprehension (p = 0.21), and greater likelihood of enrollment was observed only in individuals with better comprehension.

Conclusions: This study demonstrated that employing behavioral science-driven communication strategies for authorization for research contact had an effect on likelihood of hypothetical enrollment but did not significantly affect comprehension. Strategies using simple, positive language and visual tools may be effective and ethically appropriate. Further studies should explore how these and other approaches can help to optimize research recruitment.

Introduction

Advancing knowledge to improve clinical care depends upon research. However, recruitment and enrollment in clinical research often bottlenecks, delaying or even preventing research. Innovative tools to enhance recruitment are emerging. Increased use of electronic health record (EHR) systems has made it easier for researchers to identify eligible research participants, and many health systems have instituted ways to seek individuals' permission to be contacted directly by researchers with whom they have no prior relationship when they are eligible for a research study. These authorization for contact programs substantially expand the pool of potential participants to

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KEYWORDS

Informed consent; clinical research; recruitment; electronic health records; research ethics; survey



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whom investigators within a health system have access to and greatly enhance recruitment efforts (Cowie et al. 2017).

Some have called for greater incorporation of principles from behavioral economics in research engagement (Cohen 2013; VanEpps, Volpp, and Halpern 2016). Strategies such as nudges, manipulating defaults, or altering how choices are framed are known to affect decisions in other settings (Halpern et al. 2013; Navar et al. 2018; Purnell et al. 2015; Tversky and Kahneman 1981). More positive framing of information related to research participation could have similar effects. Patients have described concerns about negative framing within consent forms, for example (Dickert et al. 2020). However, attempts to reframe information in research recruitment more positively can raise ethical concerns, such as worries about manipulating patients to agree to participate in research they do not understand or that conflicts with their values. Unfortunately, little evidence exists regarding the effects of variations in framing or presentation of information about research-for example, using graphics versus text or neutral versus positivelyvalenced language.

Authorization for research contact is an ideal context for studying strategies employing behavioral science principles. Requests for authorization are often made electronically or when patients check in for a medical visit. At this point, communication materials are likely the main source of information patients have when deciding whether to authorize future research contact. Additionally, risks to participants from authorizing contact are low, the social value of increasing pools of eligible participants is high, and the impact of modest changes in enrollment rates may be substantial when implemented across health systems. Communication materials about authorization for contact should thus be designed to advance dual goals of enhancing enrollment and facilitating understanding.

To inform the design of materials for authorization for contact programs within a health system, we conducted an experimental study in which members of the general public were assigned to either a currentlyused flyer or one of two experimental flyers regarding authorization for contact that varied in complexity, valence, and mode of communication (graphics versus text). We hypothesized that participants who viewed the two modified flyers would be more likely to enroll and would have improved comprehension of the authorization for contact program.

Methods

Design and objective

We conducted an online survey during July 2018. Participants were randomly assigned to receive one of three versions of a flyer describing an authorization for contact program. The objective of the study was to assess whether the experimental versions of the flyer (both of which varied from the standard flyer in being simplified and positively-framed and one of which used a graphics-heavy mode of presentation) affected the primary outcome of stated likelihood of enrollment and the secondary outcome of understanding of the authorization for contact program. The study was reviewed and determined to be exempt by the Emory University Institutional Review Board. Data supporting the findings are available from the corresponding author upon reasonable requests for purposes of reproduction of results.

Setting and participants

We used the GfK KnowledgePanel, an online probability-based panel representative of the U.S. population ("GfK KnowledgePanel Recruitment and Sample Survey Methods"). Panelists receive payment administered by GfK. The KnowledgePanel has been used in prior studies regarding consent (Dickert et al. 2018; Nayak et al. 2015; Weinfurt et al. 2017). This study was conducted using the Government and Academic Omnibus service, which distributes surveys with nonoverlapping content for up to 10 days to ensure approximately 1000 respondents.

Survey development

The survey (Supplementary material, Appendix 1) was developed by investigators and pre-tested using Amazon Mechanical Turk's and TurkPrime's Mechanical Turk Toolkit to assess comprehension and solicit feedback (Litman, Robinson, and Abberbock 2017). We piloted two rounds of surveys (n = 50) and edited language after both rounds to minimize misunderstanding.

Survey administration

Participants were randomly assigned to receive one of the three flyers (Supplementary material, Appendix 2) and instructed to imagine receiving it at a doctor's office visit. All flyers had an approximately eighthgrade reading level (flyer #1-8.5; flyer #2-8.3; flyer #3-7.9) using Flesch-Kincaid scoring.

Flyer #1 was a detailed flyer currently in use that neutrally presents enrollment ("neutral text"). The neutral text flyer contained information about how to become involved in both the authorization for contact program and research generally. It included a combination of paragraphs and questions and answers, accompanied by a picture of a clinician and patient.

Flyer #2, the positive text flyer, was a simplified flyer with plain language containing bulleted information about the authorization for contact program with more positive framing of research that explicitly encouraged participation.

Flyer #3, the positive graphics flyer, had similar simplified language and positive framing as #2 coupled with a flow chart representing the contact process.

Outcome and measurements

The primary outcome was response to the question "If you were given this flyer when you arrived at your doctor's office, how likely would you be to sign up?" Participants were asked to respond to this question on a 5-point Likert scale in which 1 indicated extremely unlikely and 5 indicated extremely likely. Comprehension of authorization for contact was assessed with two questions. The first question- 'What is this flyer asking?"- was intended to assess respondents' understanding of what is being requested. The second question- 'If you sign up/agree to what the flyer is asking, are you enrolled in a research study?'was intended to assess their understanding of the implications of agreeing to the request. Understanding questions were analyzed independently, and in order to facilitate further analysis of other responses by level of understanding, answers to the two questions were combined to make a knowledge score, with 1 point assigned for each correct answer. Participants with a score of 2 were considered to have the best understanding of the flyer they received, and those with a score of 0 were considered to have the least understanding. Other questions regarding attitudes about the flyer and experience with research and the healthcare system were measured using 5-point Likert scale or multiple-choice options. Health literacy was measured by asking 'how confident are you filling out medical forms by yourself?' and was dichotomized into high (answered 'quite a bit' or higher) and low (answered 'somewhat' or lower) health literacy

(Wallace et al. 2006). Demographic data were provided by GfK.

Statistical analysis

Counts and percentages were used to summarize participant characteristics and variables of interest. Given small cell counts in certain flyer type and likelihood combinations, likelihood of enrollment was collapsed into likely, unsure/neutral, and unlikely for further analysis. Chi-square tests were performed to compare the effect of the flyers on the primary outcome of likelihood of enrollment and secondary outcome of understanding.

We performed multivariable logistic regression to investigate the association between likelihood of enrollment and flyer types. Likelihood of enrollment was dichotomized into likely (1-2) and not likely (3–5, which included unsure/neutral). Covariates included age (years), race (Black, Hispanic, Two or more Races, White and Other), education (high school of less, some college, or college graduate or more), and self-reported and dichotomized health literacy (high, low). We also performed proportional odds regression analysis to examine the effect of flyer type on the ordinal likelihood outcome variable. Because the proportional odds assumption was violated, multinomial logistic regression was then utilized (results shown in Appendix Table 3 (Supplementary material)).

To further investigate whether response to the flyer (likelihood of enrollment) depended on comprehension, we considered an interaction between flyer and knowledge score. Again, logistic regression analysis was performed using the dichotomized primary outcome variable, and multinomial logistic regression was performed using a 3-category outcome variable due to violation of the proportional odds assumption. In these models, only flyer type, knowledge score, and the interaction between the two were included.

The sample size for this study was estimated based on *a priori* assumptions of the percent likely to enroll in authorization for future contact. We assumed the most conservative baseline of 50% and hypothesized that there would be an absolute 10% difference in likelihood of enrollment with each of the novel flyers (flyers #2 and #3) as compared to the standard flyer (flyer #1). The survey mechanism used for this study sampled in waves or increments of 1000. A sample size of 1000 participants was estimated to provide 74% power to detect an absolute difference of 10% in

Table 1. Demographic characteristics.

		Flyer 1 – Neutral	Flyer 2 – Positive	Flyer 3 – Positive
	Overall	Text	Text	Graphics
Characteristic	n (%)	n (%)	n (%)	n(%)
Age*				
18–29 years	177 (16.5)	59 (18.0)	59 (15.5)	59 (16.3)
30–44 years	237 (22.2)	67 (20.4)	87 (22.8)	83 (23.0)
45–59 years	262 (24.5)	83 (25.3)	86 (22.6)	93 (25.8)
60+ years	394 (36.8)	119 (36.3)	149 (39.1)	126 (34.9)
Gender*				
Female	527 (49.3)	159 (48.5)	191 (50.1)	177 (49.0)
Race*				
White, Non-Hispanic	758 (70.8)	240 (73.2)	264 (69.3)	254 (70.4)
Black, Non-Hispanic	104 (9.7)	29 (8.8)	37 (9.7)	38 (10.5)
Other, Non-Hispanic	59 (5.5)	18 (5.5)	23 (6.0)	18 (5.0)
Two or more races, Non-	35 (3.3)	9 (2.7)	11 (2.9)	15 (4.2)
Hispanic				
Hispanic	114 (10.7)	32 (9.8)	46 (12.1)	36 (10.0)
Education*				
High school or less	361 (33.7)	108 (32.9)	127 (33.3)	126 (34.9)
Some college	327 (30.6)	103 (31.4)	114 (29.9)	110 (30.5)
Bachelors or more	382 (35.7)	117 (35.7)	140 (36.8)	125 (34.6)
Income*				
Less than \$25,000	146 (13.6)	38 (11.6)	56 (14.7)	52 (14.4)
\$25,000 - <\$50,000	206 (19.3)	66 (20.1)	71 (18.6)	69 (19.1)
\$50,000 - <\$75,000	174 (16.3)	52 (15.9)	66 (17.3)	56 (15.5)
\$75,000 - <\$125,000	335 (31.3)	106 (32.3)	116 (30.4)	113 (31.3)
\$125,000 or more	209 (19.5)	66 (20.1)	72 (18.9)	71 (19.7)
Health Literacy				
High	866 (80.9)	262 (79.9)	303 (79.5)	301 (83.3)
Low	200 (18.7)	65 (19.8)	78 (20.5)	57 (15.9)
No Answer	4 (0.4)	1 (0.3)	0	3 (0.8)
TOTAL	1070	328	381	361

*Variables used to create survey weights.

likelihood of enrollment between any two groups at a 2-sided α level of 0.05.

Analyses were conducted using SAS 9.4 (Cary, NC). All tests were 2-sided. Statistical significance was defined by p < 0.05. To adjust for noncoverage or selection bias, all analyses were conducted using post-stratification weights supplied by GfK based on Census data. Descriptive data are unweighted. Other reported data are weighted unless otherwise specified.

Results

Participants

The survey was sent to 2,038 panelists; 1070 completed it (response rate 52.8%). Half were women (49.3%) (Table 1). Overall, 16.5% of participants were age 18–29 years, 22.2% were age 30-44 years, 24.5% were age 45–59 years, and 36.8% were age 65 years or older. Participants were 73.2% White (non-Hispanic), 9.7% Black (non-Hispanic), 10.6% Hispanic, and 8.8% other (non-Hispanic) or two or more races (non-Hispanic). About one-third (33.7%) had a high school diploma or less, 30.6% had completed some college, and 35.7% had at least a bachelor's degree. Most participants (80.9%) demonstrated high health literacy, based on the self-reported single-item measure of health literacy.

Likelihood of enrollment and comprehension of flyers

Likelihood of enrolling in authorization for contact was affected by flyer assignment (p = 0.012). Among individuals assigned to flyer #1, 19.0% were likely to enroll; among those assigned to flyer #2, 24.2% were likely to enroll (p = 0.11 vs flyer #1); and among those assigned to flyer #3, 28.7% were likely to enroll (p = 0.0018 vs flyer #1).

In the logistic regression analysis controlling for age, race, education, and health literacy, participants who viewed the positive graphics flyer were more likely to enroll compared to those who viewed the neutral text flyer (OR = 1.69 95% CI [1.17, 2.44]). There was no statistically significant difference in like-lihood of enrollment between those who viewed the positive text flyer compared to the neutral text flyer (OR = 1.41 95% CI [0.97, 2.05]). Participants with a high school or less education were less likely to enroll compared to those with a college education (OR = 0.59 95% CI [0.41, 0.86]). Also, participants who identified as Hispanic were less likely to enroll compared to those who identified as White (OR = 0.58 95% CI

Table 2.	Outcomes	by flyer	type.
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Outcomes	Flyer 1 – Neutral Text weighted n(%)	Flyer 2 – Positive Text weighted n(%)	Flyer 3 – Positive Graphics weighted <i>p</i> (%)	Overall weighted n(%)	<i>n</i> -value
Likelihood If you were given this					n=0.012
flyer when you arrived at your					p = 0.012
doctor's office how likely would					
you be to sign up?					
	158.0 (48.3)	154.9 (41.0)	132.6 (36.5)	445 5 (41 7)	
Neutral/Unsure	107 3 (32 8)	131.6 (34.8)	126 7 (34.8)	365 5 (34 2)	
likoly	62.2 (19.0)	91 3 (24.2)	104.4 (28.7)	257 8 (24.1)	
τοται	327 4	377.7	363 7	1068.9	
01 - What is the flyer asking?	527.4	577.7	505.7	1000.5	n < 0.0001
For your permission to participate	26.6 (8.2)	32 4 (8 5)	25.5 (7.0)	26.6 (7.0)	p < 0.0001
in a particular research study	20.0 (0.2)	52.4 (0.5)	23.5 (7.0)	20.0 (7.2)	
For your permission to be	96.9 (30.0)	118 0 (31 4)	100 7 (27 8)	316 5 (20 7)	
contacted about participating in	90.9 (50.0)	118.9 (31.4)	100.7 (27.8)	510.5 (29.7)	
research studies (correct answer)					
For your permission to do research	00(31)	22.5 (6.0)	20.3 (5.6)	528 (50)	
with your boalth information	9.9 (3.1)	22.3 (0.0)	20.3 (3.0)	52.8 (5.0)	
All of the above	125 0 (29 7)	169 5 (11 5)	199.6 (52.0)	107 7 (15 2)	
None of the above	64.4(20.0)	26.6 (0.7)	27.7 (7.6)	402.2 (43.3)	
	222.0	279.0	27.7 (7.0)	120.7 (12.1)	
02 If you sign un/agree to what	322.9	576.9	302.8	1004.0	
Q2 - II you sign up/agree to what					
une nyer is asking, are you					
	906 (274)	1170 (211)	104 5 (28 7)	212 0 (20 2)	n 0.55
Ne (correct answer)	09.0 (27.4)	261.0 (69.0)	104.5 (20.7)	312.0 (29.2) 757.2 (70.9)	p=0.55
	237.1 (72.0)	201.0 (08.9)	239.2 (71.3)	1060.2	
IUIAL Knowledge Score Combination of	520.8	576.9	505.7	1009.5	n 0.21
Cland C2					p = 0.21
Q1 allu Q2 0 hath quastions wrong	72 1 (22 7)	106.0 (28.2)	05.9 (26.4)		
1 one question right	/5.1 (22.7)	164.2 (42.2)	95.0 (20.4) 175 1 (47.7)	2/3.7 (23.9) 507 2 (47 7)	
2 both questions right	91 2 (25 2)	104.2 (43.3)	1/3.1 (47.7)	507.2(47.7)	
	01.2 (25.2) 222 2	107.0 (28.5)	92.0 (25.4)	201.0 (20.4)	
	322.2	5/0.9	302.0	1005.9	

[0.36, 0.94]), and those with self-reported high health literacy were more likely to enroll than those with low health literacy (OR = 2.51 95% CI [1.59, 3.95)]. In the multinomial regression analysis of the three-category outcome (Supplementary material, Appendix 3), the same patterns were observed, with the exception that individuals shown both the positive text flyer and the positive graphics flyer, as compared to individuals shown the neutral text flyer, had increased odds of being likely (versus unlikely) to enroll (OR = 1.55 [1.04, 2.31] and 1.95 [1.31, 2.91], respectively).

Only 27.8% of respondents (Table 2) overall answered correctly that the flyer was asking for "your permission to be contacted for a research study." While there were no significant differences between groups in frequency of choosing the correct response, more respondents receiving Flyer 1 (20.0%) responded "none of the above" than in the other two groups (9.7% and 7.6% for Flyers 2 and 3, p < 0.001). Most participants (71.3%) understood that signing up for this program did not mean that they have signed up for a research study. Overall, 25.9% of participants had a knowledge score of 0 (lowest), 47.7% a score of 1, and 26.4% a score of 2 (Table 2). Combined knowledge score did not differ significantly by flyer type (p = 0.21).

Interaction between flyer type and knowledge score

The effect of flyer assignment was observed almost exclusively among individuals with highest comprehension (knowledge score =2) of the program (Figure 1). Among this group, those who received the positive graphics flyer were more likely to enroll (52.5%) than those who received the positive text (40.4%) or neutral text flyer (22.7%). In the logistic regression model, the interaction between flyer type and knowledge score was statistically significant (p = 0.030). Participants with a knowledge score of 2 (the highest level of comprehension) who viewed the positive text flyer were significantly more likely to enroll (OR = 2.31 95% CI [1.21, 4.41]) compared to those who saw the neutral text flyer. Those who viewed the positive graphics flyer with a knowledge score of 2 were also significantly more likely to enroll (OR = $3.76\ 95\%$ CI [1.94, 7.28]) compared to those who saw the neutral text flyer. In the multinomial logistic model, the interaction between flyer type and knowledge score was also significant (p = 0.038).

Discussion

While there has been substantial recent interest in using strategies drawn from behavioral economics to



Figure 1. Likelihood of enrollment by flyer and knowledge score.

improve research recruitment, these strategies raise potential ethical issues that must be addressed. Approaches that deliberately present research more briefly and positively than standard, lengthy forms may raise ethical concerns about omitting important information (Malik and Cooper 2018). This is one of the first experimental studies to test whether variations in framing of information and format affect likelihood of enrollment in authorization for contact.

We observed higher likelihood of enrollment using communication materials that are simpler and more positive, one of which also relied more heavily on a graphics-based format. A roughly 10% difference is only a modest effect; however, it is not inconsequential. If such a finding were translatable in practice, it could substantially increase enrollment in authorization for contact. This is because these programs are applied across entire health system. Increasing patient enrollment by 10% in a system with 1 million covered individuals, for example, would increase the number of eligible patients by 100,000. Thus, a practical implication of these data is that institutions should invest in and refine evidence-based design of system-wide recruitment materials. Doing so may enhance their ability to effectively recruit participants for clinical research; this is an important ethical goal.

The primary ethical concern about behavioral science-driven strategies tends to be about their potentially negative effects on informed consent (Cohen 2013). It is thus interesting and important that: (1) individuals with lowest comprehension of the program were less likely to enroll across all flyer types compared to those with the highest level; and (2) that the effect of the novel flyers on willingness to enroll was concentrated among individuals who best understood the flyer's content. Because it only significantly affected enrollment among those who understood authorization for contact, it does not appear that the novel flyers "duped" people into enrolling. Moreover, while flyer type did not affect comprehension overall, individuals who were exposed to the original flyer were significantly more likely to answer "none of the above" regarding what the flyer was describing. These individuals appear to have especially poor understanding of what was being requested. Thus, while superiority was not demonstrated regarding the outcome of understanding, there was a signal of potential improvement, and the novel flyers did not appear to undermine informed consent.

While we only assessed the impact of these materials in the context of an authorization for research contact program, similar issues arise regarding consent forms, advertisements, and other forms of research communication. There is a widespread tendency in these contexts to be cautious in stating the benefits of research and to avoid understating risks of participation (Dickert et al. 2020). This is driven in part by concerns about manipulation, as well as concerns regarding therapeutic misestimation and misconception, but the actual effect of these approaches in general, and in the context of authorization for contact, is uncertain (Horng and Grady 2003; Mandava and Millum 2013). Although the modifications to the framing in the flyers in this study were quite modest, our findings suggest that ethical concerns about positively presenting various aspects of research to potential participants may be overstated. It is encouraging that likelihood of enrollment among those with the lowest level of understanding was not impacted by positive framing. Thus, erring on the side of being overly cautious in descriptions of research opportunities may not be meaningfully protective but may compromise recruitment.

Our data also suggest that framing and presentation of information likely influence decisions by mechanisms other than comprehension. There may be psychological and emotional factors, for example, that are affected by how information is presented. In a study examining African-American women's intention to enroll in ResearchMatch, those who were presented with positively framed study materials and who had high self-efficacy were twice as likely to enroll as those with low selfefficacy presented with the same study materials (Balls-Berry et al. 2016). In recent work with patients related to informed consent in acute care settings, it has become clear that patients care about the tone of consent forms and other communication materials and want to feel they are being valued and being asked to contribute to something important (Dickert et al. 2020). This coheres with other work demonstrating that altruism is an important motivator for research participation. Similarly, simply having more versus less accessible language may make decisions more straightforward or easier and less burdensome for people being asked to make a decision about participation. These data do not explore various elements of research decisions in any depth, but they support further attention to and study of issues beyond comprehension in the context of research communication.

Despite the usefulness of these data, they have important limitations. Most notably, we used a hypothetical design in an online context; whether the same findings would be observed within an actual healthcare setting is uncertain. Our participants also had relatively high levels of health literacy based on a single question. The impact of communication materials may differ in individuals with lower health literacy or significant socioeconomic differences. Also, the modifications we tested are quite modest. This was deliberate, in that we intended to test modifications that we thought would be easily implementable. However, the role of more exaggerated changes to communication, either in content or valence, are important to study and may have more substantial effects. Accordingly, these data are primarily hypothesis-generating. Future studies investigating similar strategies implemented within health systems are essential. However, these data do support the claim that recruitment materials should be evidence-based and that carefully designed materials have the potential to be both practically efficacious and ethically appropriate.

Conclusions

Authorization for research contact programs have potential to increase enrollment and engagement in clinical research, but how to frame communications with patients about these programs is understudied. These data serve as proof of concept that strategies informed by decision psychology and behavioral economics may serve to increase willingness to enroll in authorization for research contact, especially among those who understand what it involves. They also provide a foundation for continuing to refine, implement, and evaluate similar approaches from the perspective of both ethics and efficiency. In addition to potentially directing strategy behind research communication, these data suggest the importance of embracing evidence-based approaches that address research recruitment scientifically while remaining sensitive to ethical considerations.

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Author contributions

CDS, CG, Y-AK, SAK, ARM, NKN, BGP, KMP, SKS, JS, BSW, and NWD contributed to the design, interpretation, drafting, and critical revision of the work, as well as the final approval of the version to be published. Data collection and analysis were completed by CDS, Y-AK, NKN, and NWD. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Disclosure statement

Dr. Sugarman is a member of Merck KGaA's Bioethics Advisory Panel and Stem Cell Research Oversight Committee; IQVIA's Ethics Advisory Panel; Aspen Neurosciences' Scientific Advisory Board; and has consulted with Portola Pharmaceutical's, Inc. Dr. Dickert reports research funding from NCATS. No other authors report any significant financial conflicts of interest.

Ethical approval

The study protocol was approved by the Emory University Institutional Review Board.

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