To pay or not to pay: Is that the question?

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Disclaimer

The views expressed are my own and do not represent the positions or policies of the NIH, DHHS, or US government

I have no conflicts of interest to disclose

Objectives:

- At the end of this presentation, participants will be able to:
  - Identify reasons to pay research participants and common ethical concerns
  - Be familiar with empirical data about payment to research participants and recruitment, understanding, and willingness to participate.
  - Understand possible models for payment and the challenges in determining amounts

To pay or not to pay?

Paying research participants

- Widespread/common
- Long-standing


Northern Virginia and Wash. DC Drivers Needed for Research Study
The Virginia Tech Transportation Institute is compensating people in the Northern Virginia and DC areas to drive their own vehicles equipped with new technology.
Up to $2,925
Neuroscience of Social Behavior
We are looking to understand how people with and without a range of interpersonal difficulties process different kinds of information. By looking at a person's brain while they play games, we can begin to understand how they make decisions. The decisions that a person makes while playing games can tell us about how a person might make interpersonal decisions in real life and what brain functions are used in the process.
You may be eligible if you:
>> Are 18-55 years old
>> Speak English
>> Are NOT claustrophobic
>> Do NOT have any metal implants (e.g. pacemakers,
>> Have NOT had a head injury
$15/hr
Participation includes:
>> Decision making games and questionnaires
>> MRI brain scan
>> Interviews about personality, behaviors, and life experiences
>> Participants will receive $15/hour and have the opportunity to ear on performance in the games
Smokers Needed for Confidential Study
$40-$500
Experimental Heavy Drinking Treatment Study
The purpose of this study is to assess the effectiveness of using a breathalyzer to facilitate an intervention to reduce alcohol use that requires no in-person cont
and the study staff during the intervention phase.
Participation includes:
>> Participants will receive compensation up to:
>> $286 for participation to offset time and effor
>> $50 bonus for completing all study requirements
>> An additional $275 based on performance within the study
>> Additional travel compensation to Roanoke may also be provided
Up to $611
Do you struggle with Type 2 Diabetes?
The Fralin Biomedical Research Institute is recruiting adults with type 2 diabetes for a research study.
Participation in this program involves:
Dietary and lifestyle coaching
Behavioral intervention
Participation is free, and you will receive:
Access to a weight loss treatment program
$300 compensation for completion of all study procedures
$300
dollarsprout
www.heyitsfree.net

Patient Recruitment Home

Current Protocols

COVID-19 Studies at the NIH Clinical Center

Payment to Research Volunteers

Ethics in Clinical Research

Faces of Research

Privacy Notice

FAQ About Clinical Studies

Contact Us

Call the **Office of Patient Recruitment** at **800-411-1222** to speak with one of our Information Specialists.
Or email us at ccopr@nih.gov

If you are deaf, hard of hearing, or have a speech disability, please dial 711 to access telecommunications relay services.

Se habla español.

Patient Recruitment

Payment to Research Volunteers at the NIH Clinical Center

Since 1954, the NIH Clinical Center, the research hospital on the NIH campus in Bethesda, Maryland, has welcomed patients and healthy volunteers from around the world to participate in medical research studies.

Some of these studies compensate for participation. We process over 20,000 payment transactions a year to both patients and healthy volunteers.

We now offer two options of payments to research volunteers: Direct Deposit and U.S Debit Card. Read more about Payment Resources.

For answers to frequently asked questions, please visit our Payment FAQ page.

This web page is a resource for payments related to your study participation only. For payments related to travel, lodging and food please contact your study team.

Paying research participants

- Allowed by regulations
- Ethically acceptable
- Perennially fraught

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FDA guidance

- Paying participants is acceptable.
- Payment …should be just and fair.
- The IRB should review the amount and the proposed method and timing to assure neither are coercive or unduly influential
- Payment should accrue as the study progresses
- Completion bonuses are acceptable provided they are not coercive or an undue inducement.
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/payment-and-reimbursement-research-subjects

Informed Consent FAQs

- What is informed consent and when, why, and how must it be obtained? +
- Is it possible to obtain legally effective informed consent to research in an urgent or emergency care setting? +
- What are the basic elements of informed consent? +
- What additional information might be appropriate to provide during the consent process? +
- Can consent or parental permission ever be "passive" or "implied?" +
- What does it mean to minimize the possibility of coercion or undue influence? +
- When does compensating subjects undermine informed consent or parental permission? +
- Can non-financial enrollment incentives constitute undue influence? +
- What constitutes coercion or undue influence when students are involved in research in a college or university setting? +
- What constitutes coercion or undue influence when employees are the subjects of research? +

https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html

Informed Consent FAQs

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Paying research subjects in exchange for their participation is a common and, in general, acceptable practice. However, difficult questions must be addressed by the IRB. ...e.g., how much money should research subjects receive, and for what should subjects receive payment -- their time, inconvenience, discomfort, or some other consideration -- IRBs must be sensitive to whether any aspect of the proposed remuneration will be an undue influence, thus interfering with the potential subjects' ability to give voluntary informed consent...Remuneration ...should be just and fair.

https://policymanual.nih.gov/3014-302

Paying research participants

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CIOMS Guideline 13

- Participants should be reasonably reimbursed for costs incurred and compensated reasonably for their inconvenience and time spent.

- Compensation must not be so large as to induce potential participants to consent to participate in the research against their better judgment ("undue inducement").

- Are research participants paid *enough*? … ought to change the default to favor, rather than encourage suspicion of, offers of payment to research participants. Largent and Fernandez-Lynch 2017

Paying research participants

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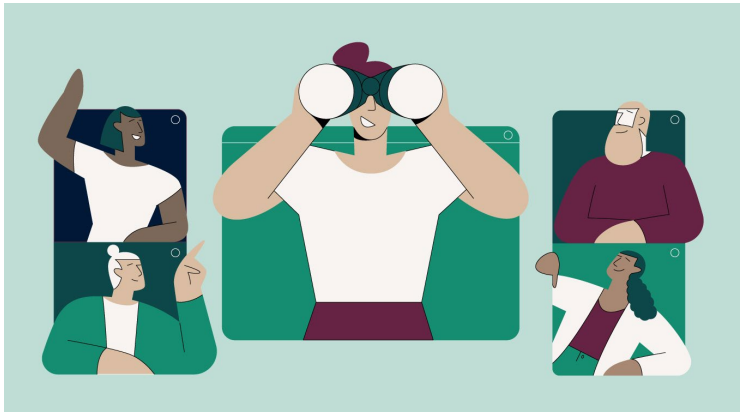
- Why do we pay research participants, and What are the concerns?

Why do we offer payment to research participants?

- To help recruitment and enrollment which can increase the chances of timely study completion.

- Good for social/scientific value of research

Recruitment



Recruiting and retaining the target number of eligible participants is a frequent challenge, delaying and underpowering trials

"...any and all means to increase enrollment and retention..."
ISR 2014

Payment and enrollment

- How well does offering payment increase the rate of enrollment?
  - Survey response rates
  - Healthy volunteer studies
  - Clinical trials

Payment and response rates

- Increases survey response rates
- Money more effective than vouchers or lotteries.

Abdelazeem B et al.(2023) Does usage of monetary incentive impact the involvement in surveys? A systematic review and meta-analysis of 46 randomized controlled trials. *PLoSONE* 18(1):e0279128. https://doi.org/ 10.1371/journal.pone.0279128

The major reason that healthy volunteers enroll in studies is for the money. However, healthy volunteers consider risk more important to their enrollment decision than the money being offered.

Healthy volunteers also sometimes have other motives, including curiosity, altruism, sensation seeking, knowledge, etc. Stunkel and Grady More than the money: a review of the literature examining healthy volunteer motivations. *Cont Clin Trials* 2010

Table 2 Recruitment intervention and effect on participation

Recruitment intervention[Reference ID]	Increases	Decreases	Little impact	Inconclusive
Trial design				
Open design[16 32]	●			
Placebo*[59]		⊙		
Patient preference design[18]			⊙	
Zelen design†[25]		⊙		
Internet-based data capture†[42]		⊙		
Obtaining consent				
Process—opt-out approach[55]	⊙			
Process—consent to experimental treatment*[48 50]			●	
Process—consent to standard treatment*[48 50]			●	
Process—refuser chooses treatment option*[50]			⊙	
Process—physician modified chance of experimental*[48]			⊙	
Process—participant modified chance of experimental*[48]			⊙	
Form—researcher read aloud[56]			⊙	
Form—altered readability level†[19]			⊙	
Approach to participants				
Delivery—video presentation*†[28 35]			●	
Delivery—video presentation plus written information[60]	⊙			
Delivery—audiovisual overview of trials[21 22 33]			●	
Delivery—interactive computer presentation*[36 44]				●
Delivery—verbal education session[45]	⊙			
Supplementing info—booklet on clinical trials*[23 34]			●	
Supplementing info—study-relevant questionnaire[31 37]			●	
Supplementing info—newspaper article[51]			⊙	
Framing—treatment as faster*[52]	⊙			
Framing—treatment as new*[38]		⊙		
Framing—emphasis on pain or risk*[54]		⊙		
Framing—positively or negatively*[43]			⊙	
Content—more detailed info (inc. total disclosure)*[27 53]			●	
Content—financial disclosure of investigator interest*†[57 58]		●		
Telephone reminders[31 49]	●			
SMS messages[26]	⊙			
Eligibility screening—face-to-face*[24 29]				●
Eligibility screening—telephone*[20]	⊙			
Eligibility screening—electronic self-complete*[29]			⊙	
Screening personnel[46]			⊙	
Financial incentives				
Cash incentive with invitation[26]	⊙			
Paid participation*†[17 30]	●			
Level of trial risk*†[17 30]				●
Training for recruiters				
Training lay advocates†[40]	⊙			
Education sessions†[39]			⊙	
Trial co-ordination				
On-site visits†[41]			⊙	
Additional communication†[47]			⊙	

●, Multiple studies; ⊙, single study.
*Includes recruitment to hypothetical trial(s).
†Includes result reported by study authors only (effect size not calculated).

Treweek S. et al Methods to Improve Recruitment to Clinical Trials Cochrane Review. *BMJ Open* 2013

*3 trials- two hypothetical

Approach to participants

using video or other audiovisual materials had mixed

Table 2. Outcomes by Group in the 2 Embedded Randomized Clinical Trials

	Smoking trial				Ambulation trial			
Outcome[a]	$0	$200	$500	*P* value	$0	$100	$300	*P* value
No.	216	217	221		216	212	214	
Consent rate, No./total No. (%)	47/216 (21.8)	78/217 (35.9)	104/221 (47.1)	<.001	98/216 (45.4)	102/212 (48.1)	92/214 (43.0)	.62
Perceived risks of the research, No./total No. (%)								
Some risk	102/216 (47.2)	106/217 (48.8)	112/221 (50.7)	.32[b]	8/216 (3.7)	5/212 (2.4)	13/214 (6.1)	.38
Time spent reviewing consent, s								
All, median (IQR)	908 (411.5-1283.8)	710.5 (436.5-1429)	1106.5 (579.2-1507.5)	<.001	298 (195.5-446)	298.5 (169-431)	323 (175-592)	.004
Risk section, median (IQR)	155 (73.5-321)	137 (59.25-257.5)	179 (100-361)	<.001	32 (13-53)	27.5 (14-48.25)	32.5 (11.25-59.75)	.16
Incidence of TM, No./total No. (%)								
Possible TM	5/47 (10.6)	8/78 (10.3)	12/104 (11.5)	.83	3/98 (3.1)	1/102 (1)	0/92 (0)	.07
Likely TM	1/47 (2.1)	0/78 (0)	1/104 (1)	.65	1/98 (1)	0/102 (0)	0/92 (0)	.22
Understanding of the trial								
Median % (IQR)	66.7 (66.7-88.3)	66.7 (50-83.3)	66.7 (50-83.3)	.78	100 (83.3-100)	100 (83.3-100)	100 (83.3-100)	.97
Perceptions of influence of coercion, No./ total No. (%)								
Some coercion	10/47 (21.3)	23/78 (29.5)	25/104 (24)	.91	4/98 (4.1)	4/102 (3.9)	6/92 (6.5)	.44

Abbreviation: TM, therapeutic misconceptions.

[a] Except perceived risk of research, the rest of the outcomes were analyzed among the consented sample.

[b] Adjusted *P* value from the logistic model.

Halpern SD et al. *JAMA Internal Med* 2021
https://jamanetwork.com/journals/jama/fullarticle/10.1001/jamainternmed.2021.5450?utm_campaign=articlePDF%26utm_medium=articlePDFlink%26utm_source=articlePDF%26utm_content=jamainternmed.2021.5450

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Does payment increase recruitment of underrepresented groups?

- Payments marginally improved recruitment into some trials, but no evidence that it broadened participant demographics Jennings CG et al. Does offering an incentive payment improve recruitment to clinical trials and increase the proportion of socially deprived and elderly participants?. *Trials* 16, 80 (2015). https://doi.org/10.1186/s13063-015-0582-8

- Low-income individuals requested similar payment for participation as high-income peers (hypothetical study); higher payment may be necessary to increase participation overall and of Hispanics. Walter J, et al. Research Participation by Low-Income and Racial/Ethnic Minority Groups: How Payment May Change the Balance, *Clinical Translational Science* 2013. https://doi.org/10.1111/cts.12084

- Approaches to payment that leave participants financially worse off are unfair, especially to those of lower SES. Bierer BE, et al. Fair payment and just benefits to enhance diversity in clinical research..*Journal of Clinical and Translational Science* 2021:

Costs of research participation

- Clinical trials can pose substantial financial burden including from health-related costs and indirect costs related to travel, lost wages, and lodging.

- Populations at highest risk for financial toxicity are exactly those less likely to participate in clinical trials.

- Skewed participation may limit the external validity of clinical trial findings, making a balanced patient population important to the general applicability of results.

Chino F, Zafar Y. Financial Toxicity and Equitable Access to Clinical Trials.2019 ASCO Educational Book. http://asco.org/edbook

Cost as a barrier

- Research shows that patients from underrepresented and under-resourced communities are more likely to experience poverty and have poor health outcomes…

- Research can leave these populations behind
- … a 2021 study found that one of the top five barriers to increasing participation of patients from historically underrepresented racial/ethnic backgrounds in clinical trials was “time and resource constraints associated with participation.”

PATIENTS, POVERTY, AND PARTICIPATION IN RESEARCH: THE HIDDEN COSTS OF DISEASE AND SOCIOECONOMIC STATUS January 30, 2023
https://nationalhealthcouncil.org/blog/patients-poverty-and-participation-in-research-the-hidden-costs-of-disease-and-socioeconomic-status/

Other reasons to offer payment

- Enable participation
- Make participation +/- revenue-neutral
- Compensate for time, contribution, risk
- Minimize possibility of exploitation
- Demonstrate respect and gratitude

(Payment for any of these reasons might also facilitate recruitment and inclusion of diverse groups)

What are the ethical concerns?

- Coercion
- Undue influence or inducement
- Unjust inducement
- Exploitation
- Deception

Gelinas et al. *NEJM* 2018;378:766-771;
Grady C. *J of Clin Investigation* 2005; 115(7): 1681–16872
Largent, Lynch. *Yale J Health Policy, Law, Ethics* 2017;17:61-8

Coercion

- Coercion involves threatening to make someone worse off by violating their rights or depriving them of something to which they are entitled, creating a circumstance in which the person has no reasonable alternative but to comply.
  Wertheimer A. Coercion. Princeton University press, 1987, SACHRP
- Classic example:

- The offer of payment can make someone *better* off, not worse off. Payment is not coercive.

Wertheimer A, Miller FG. Payment for research participation: a coercive offer. *J Med Ethics* 2008; 34(5): 389–392. SACHRP https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-a-september-30-2019/index.html

Undue Influence or Inducement

- Undue inducements- offers whose attractiveness distorts individuals' judgment, *inducing* them to do something unreasonable or against their own interests (blinded by the money).
- Inducements are part of everyday life, encouraging people to do reasonable things they might not otherwise do.

Undue influence

- Undue influence occurs when there is an (1) excessive offer of something valuable or desirable that leads to (2) poor judgment or a compromised decision-making process, which in turn leads to (3) a decision to engage in harmful activity that seriously contravenes the decision-maker's interests or obligations. SACHRP 2019 https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-a-september-30-2019/index.html#:~:text=SACHRP%20recommends%20that%20OHRP%20and,thank%20them%20for%20their%20contribution.

undue influence

- …when it appears likely to inhibit potential participants' adequate consideration of, and reflection about, important study features, such as risks, burdens, and discomforts, and impair their understanding of the research and their participation in it. SACHRP 2019

Undue inducement- ignoring study details?

High participation payments “increased perceived risk and time spent viewing risk information.” Cryder et al. *Soc Sci Med* 2010;70:455-464, Halpern SD et al *JAMA Internal Med* 2021

Those with a primary financial motivation had higher comprehension score than those reporting other motivations. (12.0 ± 2.3 versus 10.3 ± 2.9 (p =0.0005)

Stunkel et al. *IRB: Ethics & Research, 2010, 32(4): 1-9*

Ignoring study risks?

Money increased respondents' WTP in research, regardless of risk level. Willingness to enroll decreased as risk increased, not attenuated by higher payment. Bentley, Thacker. *J Med Ethics* 2004;30:293-298

Although increasing payments motivated greater WTP, participation rates dropped equivalently with increasing risks across all payment levels. Halpern et al. *Arch Intern Med* 2004;164:801-803

As noted, healthy volunteers in phase 1 drug studies, motivated by money, rated risk as more important to their enrollment decision than money. Grady C et al. *Clin Trials*. 2017;14(5):526-536.

Healthy volunteers are generally aware of and reflective about Phase I trial risks. The majority thought that Phase I trials were medium, high, or extremely high risk, but nonetheless felt that they were personally safe from harm. Fisher JA et al. *PLoS Med* 2018; 15(11);e1002698

Unjust Inducement

- Do incentives unjustly increase the extent to which research relies on the poor?

- Positive interaction between income and the influence of payment on WTP (P =.09), payment more strongly influences WTP among wealthier people. Halpern et al. *Arch Intern Med* 2004;164:801-803

- Small incentives had little impact on the participation of poorer individuals, but larger incentives ($500) eliminated the disparity in participation rates. Dutz et al: https://bfi.uchicago.edu/working-paper/what-drives-gaps-in-scientific-study-participation-evidence-from-a-covid-19-antibody-survey/

Exploitation

- Exploitation is taking unfair advantage. Thought to occur when research participants do not receive fair benefits given the risks/burdens they face and the extent to which others benefit from their involvement.

- Payment might increase the extent to which participants benefit, reducing the chance of exploitation.
- Many thus argue for paying more. Low or no payment would be more exploitative

Deception

One study found that of 100 participants in at least two trials: 32% concealed health problems, 28% concealed medications, 14% pretended to have a condition. Concealment was correlated with greater interest in monetary rewards. Devine et al. *Clin Trials* 2013;10:935-948

Incentive payments may lead participants to lie about their medical history in order to be eligible, or deny side effects to avoid being dropped. Dickert. *Clin Trials* 2013;10:840-841

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CLINICAL TRIALS

When science goes wrong—misrepresentation, coercion, and undue influence when paying research participants

Paying people to take part in clinical research has always been an ethical minefield. **Linda Nordling** reports on pushback from researchers and participants alike

Linda Nordling *freelance journalist*

In 2019 Stephan Boese-O'Reilly noticed something strange in urine collected from miners in Zimbabw
The German paediatrician and public healt
was in the country to study mercury poi
mining communities of Kadoma, so
Harare. The town had once had a
industry, but when cheap clothe
the market its people started d

Up to 20 million people world
small scale gold miners. But
high. The miners use mercury
which is locked in the ore they
pits. The gold and the mercury
which is heated to evaporate the
the gold nugget behind. The proces
fumes, which the miners and their fa
in. Mercury, a neurotoxin, can affect coord
harm vital organs, and cause developmental
problems in children.

Fifteen years before, in 2004, Boese-O'Reilly and his colleagues had found significantly elevated mercury levels in urine collected from Kadoma miners. This time, however, despite an increase in mining activity, average mercury levels were much lower.

Despit in the clinical research
receiving
penses.

colleagues had found significantly elevated mercury levels in urine collected from Kadoma miners. This time, however, despite an increase in mining activity, average mercury levels were much lower.
Although perplexed at first, ...team quickly realized what had happened. A compensation payment of $5 for participants had attracted not just miners, but also salaried workers from Kadoma's downtown offices. These had misrepresented themselves as miners to access the payment—something that had not happened before, when the study was performed in the mining areas and not in the town.

efit" does
pants will not view it
ne of the criticisms levelled at paying for
arch participation—especially in early stage trials where healthy volunteers are paid often relatively large sums to take part—is that it tends to attract people who are hard up for money, who might therefore accept a higher degree of risk when

Minimizing deception

- Advertisements, Amount of payment, Screening, Assessing motivations, Attending to data inconsistencies, Use subject registries Devine E et al. Strategies to exclude subjects who conceal and fabricate information. *Cont CT* 2017.

- Misrepresentation in other trials?

Ethical concerns

- Money is not coercive
- Too much worry about undue influence. People often make rational choices to accept more risk for more money but without blinding them to risk, others have different motivations for participating.
- Variation in the population distribution of research risks/benefits is driven by many factors
- We should take steps to minimize deception and misrepresentation, and maximize understanding

How much to pay?

Models for paying research participants

- Reimbursement model (expenses)

- Market model (incentives)

- Wage payment model (compensation)

- Appreciation model

Dickert N, Grady C. *NEJM* 1999

IRB Member Views (N= 610)

- 61% of respondents were somewhat, moderately, or very concerned by payment in *any* amount.

- 87% were somewhat, moderately, or very concerned by substantial payment. Largent et al. *IRB* 2012;34:1–8

- Majority had substantial misconceptions about coercion and undue inducement. Largent et al. *Bioethics* 2013; 27(9): 500-507

Blog / Research

How much research participants want to be paid

By Ian Floyd and The Decision Lab | 9 min read | Updated Oct 24, 2023

Good research is almost always incentivized. And people want money for taking part in research. But how much should you offer?

Deciding on the right incentive amount is a delicate problem: pay too little, and you won't get enough participants. Pay too much, and you blow up your budget. We did some research to find out the right amount to offer to keep both your participants and your budget happy.

https://www.tremendous.com/blog/how-much-research-incentives-pay-participants/

Deciding how much to offer to research participants

- Benchmarks?
- Reasons for paying
- Study design and details
- Participant contributions/vulnerabilities
- Budget
- Fair and just
- Consideration of institutional guidelines, local societal, legal, cultural norms
- When and how to pay

Box 1. Considerations for Investigators Proposing Payment Offers

- Clearly communicate the rationale for payment amounts to the IRB by itemizing payments according to the following categories: reimbursement for out-of-pocket expenses, compensation for time and burdens, or recruitment incentive. Include justification for specific amounts proposed.
- Focus first on treating participants fairly by reimbursing and compensating them for participation before assessing whether incentive payments are needed.
- Plan to reimburse participants for out-of-pocket expenses unless there are strong countervailing reasons against doing so.
- Consult with the IRB on what types of expenses and amounts the IRB considers reasonable for reimbursement.
- Consider compensating participants for their time commitment and the burdens they assume.
- Provide justification for why the compensation rate proposed should be considered fair, drawing analogies to nonresearch contexts such as employment.
- Propose payment as a recruitment incentive only when proposing to offer more than would be justified for reimbursement and compensation.
- When possible, offer options for insurance coverage for participants (or other mechanisms of financial protection) in order to compensate for reasonable expenses arising from research-related injury.
- When compensation or recruitment incentive is offered, consider increasing safeguards around participant comprehension and informed consent, particularly as payment amounts increase. Include measures to assess comprehension (e.g., having participants explain key aspects of research in their own words) as appropriate.

Gelinas L et al. *NEJM* 2018; 378;8: 766-771

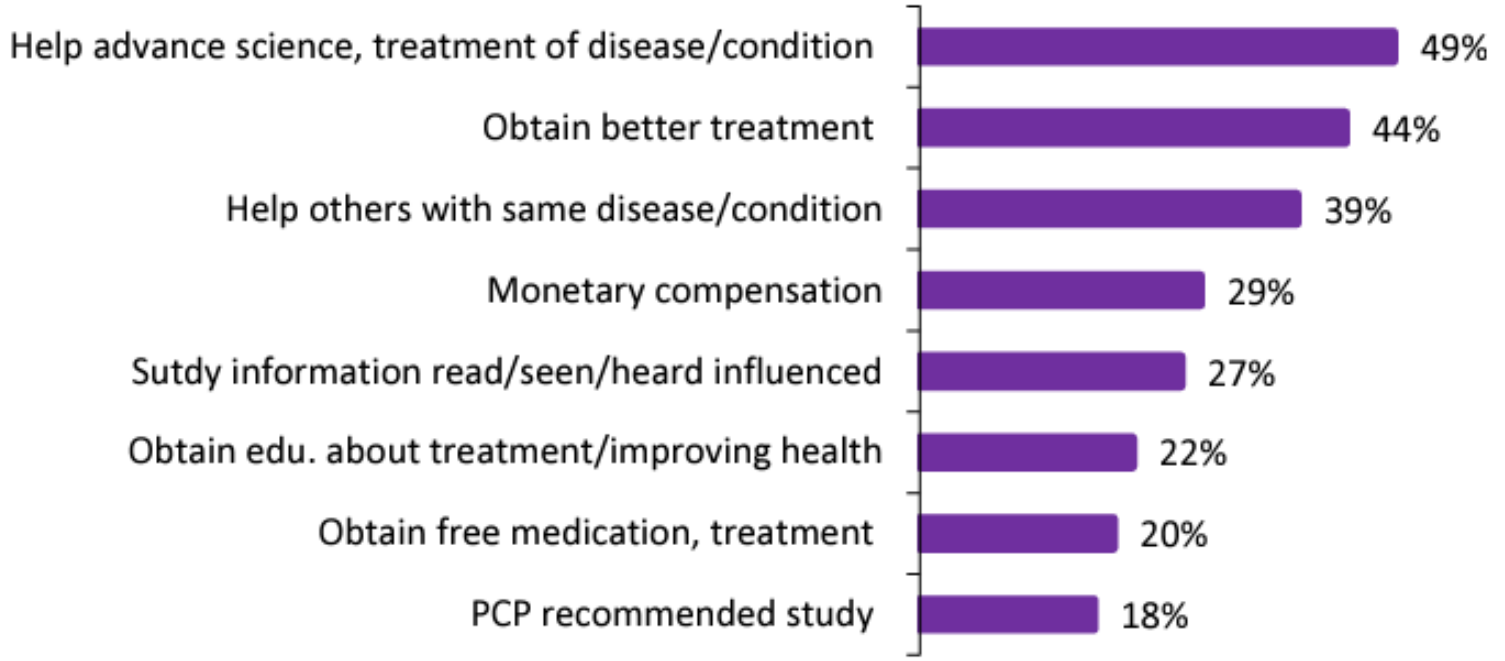
Paying research participants

- Reimbursing expenses should be standard
- Compensation for time and inconvenience is fair and respectful
- Incentives may be useful
- Payment is acceptable by regulation and ethical analysis

- Offering money is not coercive, is unlikely to result in unjust inducement, may promote understanding and likely reduces the chance of exploitation
- Take steps to reduce the chances of undue influence (rare) and of misrepresentation or deception

THANK YOU

Top participation reasons



Sample Size = 2,194, Base: Clinical trial participants, Red shaded cells indicate statistical significance within row at the 95% CL