



August 24, 2026

The Honorable T. March Bell
Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

Re: Request for Information Regarding the Federal Anti-Kickback Statute and Beneficiary Inducements CMP; [File Code OIG-2602-N](#)

Submitted via Regulations.gov

Dear Inspector General Bell:

Research!America submits these comments in response to the Office of Inspector General's Request for Information Regarding the Federal Anti-Kickback Statute and Beneficiary Inducements CMP (OIG-2602-N). [Research!America](#) is a nonprofit, nonpartisan alliance dedicated to making research and innovation a higher national priority and accelerating medical progress. Our members include patient advocacy organizations, academic medical centers, universities, research institutes, scientific societies, public health organizations, philanthropies, and private-sector innovators across the United States.

Research!America appreciates the opportunity to comment and welcomes OIG's examination of whether current federal rules may create unintended barriers to clinical trial participation. Clinical trials are essential to turning scientific discoveries into new treatments and cures for patients. Clear and practicable policies can reduce avoidable barriers to participation, strengthen clinical research, and accelerate medical progress, while maintaining appropriate safeguards against improper financial influence.

Consistent with our mission, Research!America supports policies that advance medical and scientific research and help translate discoveries into better health. That includes congressional efforts to reduce barriers to clinical trial participation, such as the bipartisan [Clinical Trial Modernization Act](#), introduced in both the House and Senate. Among its proposals, the legislation would protect certain assistance for expenses associated with

clinical trial participation. It would also establish conditions under which drug or device manufacturers or their agents could assist with participants' cost-sharing obligations.¹ The legislation addresses several of the same issues raised in this RFI, and we encourage OIG to consider these proposals as it explores paths to responsibly expand access to clinical trials.

Our comments address Questions 1 and 2 and the portions of Questions 3, 11, 13, and 14 that relate to patient participation, appropriate forms of participant support, regulatory clarity, and the broader implications for clinical research and medical progress.

Question 1: Can Participant Support Facilitate Participation?

Participant support cannot address every barrier to clinical trial enrollment, such as limited awareness, restrictive eligibility requirements, or the lack of a nearby trial. It can, however, reduce financial and logistical burdens that may prevent an eligible patient from enrolling or remaining in a trial. This matters because clinical trials are essential to evaluating new treatments and improving the standard of care. Without enough participants, trials may close prematurely, wasting resources, leaving important scientific questions unanswered, and delaying the availability of new treatments.²

In a [2023 Morning Consult](#) survey conducted on behalf of the PAN Foundation among 1,503 adults with chronic illnesses, 84% said costs and reimbursements would influence their willingness to participate in a clinical trial. The same percentage cited trial location, and 83% cited distance. Among respondents who had never participated, 23% identified lack of transportation and 30% identified distance to the study site as reasons for not participating.³ A prospective study of 1,262 patients with breast, lung, or colorectal cancer also found that patients with annual household incomes below \$50,000 had 32% lower odds of participating than patients with higher incomes.⁴ Although these studies were not limited to federal health care program enrollees, they illustrate how financial and logistical burdens can influence patients' ability and willingness to participate.

Assistance with transportation, lodging, meals, childcare, cost-sharing, and lost income cannot bring a trial closer to a patient, but it can make traveling to that trial more manageable. Providing necessary digital technology may also allow some trial activities to take place remotely. Clear federal policies permitting reasonable support for these costs could therefore help more eligible patients enroll and remain in clinical trials.

Question 2: Can Current Federal Rules Create Barriers?

Potentially, yes. Current law does not clearly protect all reasonable forms of assistance for clinical trial participants. OIG has issued favorable advisory opinions permitting certain arrangements that waive or subsidize health care cost-sharing obligations for clinical trial participants. Those opinions, however, apply only to the requestors and the specific arrangements reviewed. Other sponsors and trial sites cannot automatically rely on those opinions as legal protection for their own participant-support arrangements.⁵

The absence of clear, broadly applicable protection may make organizations hesitant to help with transportation, lodging, childcare, stipends, and other trial-related expenses. In a [February 2026 letter](#) to OIG, 25 patient, research, and medical organizations reported that many sponsors are reluctant to cover participants' nonmedical expenses because of concerns that doing so could violate federal law.⁶

The bipartisan Clinical Trial Modernization Act also reflects concern that current law may discourage appropriate participant assistance. The introduction of legislation reinforces the need for OIG to examine whether current protections are sufficiently clear and broadly available.¹

Together, these developments indicate that organizations need clearer, more broadly applicable protections for reasonable participant support.

Question 3: What Forms of Support May Help?

From Research!America's perspective, the forms of support most directly connected to participation barriers include reasonable assistance with transportation, parking, lodging, meals, childcare, cost-sharing, and other expenses incurred because of clinical trial participation. Compensation for time away from work or caregiving responsibilities may also be relevant, as may necessary technologies that allow individuals to participate remotely.

A 2024 article in [Clinical Researcher](#) described burdens including lost wages, travel expenses, time away from work, childcare needs, and health care costs not fully covered by insurance or study reimbursement. The authors also noted that digital tools may reduce



geographic barriers, although some participants need devices or internet access to take advantage of remote participation options.⁷

OIG should distinguish among reimbursement for expenses, compensation, and incentives. Reimbursement offsets costs a participant has incurred, compensation recognizes the time, inconvenience, and other demands of participation, and incentives provide an additional benefit to encourage a person to enroll or remain in a trial. Because these forms of support serve different purposes and may raise different considerations, OIG should account for those distinctions when developing appropriate safeguards.

Research!America does not have the operational data needed to recommend payment levels or assess how frequently each form of support is offered, which forms are ineffective, or which arrangements present heightened legal risks. We encourage OIG to rely on evidence from participants, trial sites, sponsors, Institutional Review Boards, and legal and compliance experts on those questions.

Questions 11 and 14: Where Is Greater Clarity Needed?

Clinical trial sponsors and research sites need clear rules about what support they may provide to participants. As discussed above, OIG's advisory opinions address only specific organizations and arrangements, leaving other sponsors and sites uncertain about whether they may offer similar support.

OIG could help by providing straightforward guidance and examples showing when organizations may cover expenses. Guidance may not be enough when current law does not clearly protect a particular form of support. In those cases, OIG should consider creating or modifying a safe harbor or CMP exception, which would provide more broadly applicable protection.

These policies should make it easier to address legitimate participation costs while protecting patients from pressure, improper financial influence, or being directed toward unrelated health care services. Research!America is not positioned to recommend specific payment limits or legal requirements. In developing those details, OIG should prioritize a framework that is well-defined and informed by the practical realities of conducting and participating in clinical trials.



Question 13: What Are the Broader Implications?

Reasonable support could enable more patients, including people enrolled in Medicare, Medicaid, and other federal health care programs, to participate when transportation, childcare, lost income, or similar costs would otherwise prevent them from doing so. Reducing these barriers may improve access, particularly for patients with limited incomes or those who live far from trial sites.

Higher and more representative enrollment can have benefits that extend beyond individual participants. Trials that enroll and retain enough people are more likely to be completed successfully and produce timely, reliable results. Including patients with a broader range of backgrounds and circumstances can also help researchers understand whether a treatment is safe and effective for the people who will ultimately use it. In turn, stronger evidence can help clinicians, patients, regulators, and other decision-makers make better-informed choices.

Adequate enrollment also helps protect the time and resources already invested in a study. When trials close early because they cannot recruit enough participants, important scientific questions may go unanswered. Reducing avoidable participation barriers can help research move forward more efficiently, improve the translation of discoveries into medical progress, and make new treatments available to patients sooner.²

Conclusion

Research!America encourages OIG to pursue clear, implementable policies that allow reasonable participant support while protecting patients from coercion, improper financial influence, and steering. Research!America appreciates OIG's consideration of these comments.

Sincerely,

A handwritten signature in black ink that reads "Ellie Dehoney".

Ellie Dehoney
Senior Vice President, Policy and Advocacy
Research!America

References

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3. PAN Foundation, Clinical Trial Awareness and Participation: Survey Research Results (January 2023), https://www.panfoundation.org/wp-content/uploads/2023/05/PAN-Clinical-Trials_Survey_2023.pdf
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6. American Cancer Society Cancer Action Network et al., “Partner Letter to HHS Office of Inspector General Regarding a Safe Harbor for Clinical Trials” (Feb. 9, 2026), <https://www.lung.org/getmedia/f446f2dd-c137-445a-8eba-92ad0ae1615b/Partner-Letter-to-HHS-Office-of-Inspector-General-re-Safe-Harbor-for-Clinical-Trials.pdf>
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