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# Transparency of Participant Incentives in Hiv Research

Brandon Brown  
*University of California*

Jerome T. Galea  
*Harvard Medical School, jeromegalea@usf.edu*

Peter Davidson  
*University of California*

Kaveh Khoshnood  
*Yale University*

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## Transparency of participant incentives in HIV research

**Brandon Brown, Jerome T Galea, Peter Davidson, and Kaveh Khoshnood**

Center for Healthy Communities, Department of Social Medicine and Population Health, UCR School of Medicine, Riverside, CA, USA (BB); Department of Global Health and Social Medicine, Harvard Medical School, Boston, MA, USA (JTG); Socios En Salud, Sucursal Peru, Lima, Peru (JTG); University of California, San Diego School of Medicine, Division of Global Public Health, UC San Diego Central Research Services Facility, La Jolla, CA, USA (PD); and Yale School of Public Health, New Haven, CT, USA (KK)

Incentives in research encourage participation, can help to fairly compensate participants for time and effort, and can retain study participants in sufficient numbers.<sup>1–3</sup> However, little attention has been given to defining what constitute fair incentives, even in HIV research, which often includes vulnerable populations. Neither the Council for International Organizations of Medical Sciences (CIOMS) guidelines<sup>4</sup> nor the US Code of Federal Regulations<sup>5</sup> specifically address incentives, and there are few empirical data for defining undue influence of incentives in research, including medical benefits.<sup>4,6,7</sup> Still, the proposed revisions to the CIOMS guidelines state that compensation must not cause undue inducement, which itself is difficult to judge, acknowledging that studies on the topic are needed.

All research with human participants requires voluntary participation, yet even within one topic (ie, HIV) the risks, costs, and benefits of each study vary substantially leading to diverse incentive types and amounts.<sup>8</sup> Incentive variability persists across similar protocols, and few institutions track the proportion of their studies providing incentives.<sup>6,9</sup>

The absence of guidance on incentives is a particular problem in HIV research because participants often face more than minimal risk, and the epidemic is concentrated in key populations who may be socially marginalised and more likely swayed by incentives.<sup>10,11</sup> Fabrication, exaggeration, or concealment of symptoms and behaviours may result if potential participants perceive the incentives as irresistibly attractive compared with the perceived risks.<sup>12</sup> People involved in multiple simultaneous studies might take shortcuts through studies offering minimal incentives to move on to those with larger incentives, thereby harming the science of lower paying studies.<sup>12</sup> Inadequate incentives are also emerging as a topic of research particularly in low income communities where providing benefits may be considered an ethical responsibility.<sup>13</sup>

Incentives can affect the translation of clinical trial results to real world adoption and effectiveness. For example, if the incentive for each visit in an HIV drug efficacy study is

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Correspondence to: Brandon Brown.

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high, participants are more likely to return for subsequent visits and to receive a complete round of treatment. However, if the same incentive amount is unavailable after drug approval, overall effectiveness might drop because of low adherence rates. For example, results from both the VOICE study and iPrEx showed that participants were enthusiastic to join the research, but adherence was low, thereby harming the scientific integrity of the studies.<sup>14,15</sup> Future studies could examine the effect of incentives on adherence, and modify the incentive if necessary to ensure the best results.

In some cases there may be no effect on research outcomes, but a transparent and publicly available database of incentives could help to understand these effects better.<sup>16</sup> Access to transparent and searchable incentive and payment data can serve several essential functions both in the HIV field and more broadly, for example, it might assist with decisions on incentives in new studies, stimulate discussions with stakeholders on previous incentives provided to ensure fairness, provide a solid argument for the need to disclose incentives in publications, advance cost-benefit analyses of incentives used for recruitment and retention, promote a data-driven approach to better define fair incentives, and improve the transition from efficacy to study effectiveness. To achieve these goals, researchers must make a commitment to populate the incentives database, to use it for decision making, and to share it with their research partners. Even without a database, immediate action should be taken: for funders to require that incentives are reported in ClinicalTrials.gov and for authors and editors to ensure that incentives are disclosed in publications.

The concept of full reporting is not novel but has been difficult to implement. Decisions on incentives can and should be made in a systematic way, taking into account the heterogeneity of clinical studies, the study population, and the subtleties of the research question. Considering its well known commitment to social justice, the HIV research community should lead the way in addressing incentive transparency.

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