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Recommendations for 'Pay-to-Play' Have Wider Application

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At its recent meeting,[1] one of the most influential and high-ranking federal advisory committees on human subjects research adopted recommendations to help investigators craft and institutional review boards (IRBs) assess the merits of studies referred to as "pay-to-play."[2]

Participants are charged to enroll in such studies, paying partial costs or sometimes making significant investments to receive unapproved or investigational drugs or other products. (Blood transfusions and purported gene therapies are two examples.)

The HHS Secretary's Advisory Committee on Human Research Protections (SACHRP) developed five considerations for IRBs to ponder when faced with such studies. In addition, NIH asked SACHRP to "consider whether there are questions that prospective subjects should ask, or objective criteria that they should consider, that are unique to pay-to-participate trials and that would facilitate understanding of any implications of participating," the committee explained in the recommendations.