COSMOS
Navigate the Compliance Universe

Report on Research Compliance Volume 16, Number 11. November 01, 2019
SACHRP Approves Recommendations to Assist Institutions With 'Pay-to-Play' Studies

By Theresa Defino

Although it is "best to avoid charging" participants to take part in research, such studies do arise, presenting institutional review boards (IRBs) with new challenges in assessing them. Even NIH has sought insights on this kind of study, often referred to as "pay-to-play."

In fact, NIH asked the HHS Secretary's Advisory Committee on Human Research Protections (SACHRP) to develop "questions that prospective subjects should ask, or objective criteria that they should consider," recognizing there are some unique features and implications to such studies. The Food and Drug Administration (FDA) also reportedly asked SACHRP for its wisdom on the subject for IRBs.

At its Oct. 16 meeting,[1] SACHRP delivered on that request, approving a nine-page document that will now go to HHS for possible adoption and dissemination. Although the vote to approve the document was unanimous, it came after last-minute changes suggested by new industry representatives on the committee to delete language from an introductory section that included a phrase stating that, for industry, "there is little motivation to fund research that is unlikely to generate profit."

Following seven recent appointments, SACHRP has a full complement of 11 members (for now; more vacancies will occur soon). Of the seven new members, three are from pharmaceutical companies, three are from universities, and one represents patients.[2]

Pay-to-play studies are more formally called "pay-to-participate." There may be no regulatory requirement for IRBs to review such studies, but they are nonetheless "increasingly" being asked to do so, according to SACHRP.

However, "IRBs may face the greatest difficulty in review and oversight when pay-to-participate trials involve medical products that are not clearly regulated by [the] FDA as drugs, biologics or devices—for example, nutritional supplements, surgical procedures, autologous stem cell transplants meeting minimal manipulation and homologous use criteria, and novel applications of standard treatments," SACHRP's document states.

Attention was drawn to these types of studies several years ago when a company began charging thousands of dollars for transfusions of so-called "young blood," purportedly as part of a clinical trial.

After a general warning from the FDA earlier this year, the firm changed its tack but is still in business, charging $8,000 to $12,000 per transfusion. Its website now states: "In August 2019, the FDA decided that blood sourced specifically from young donors is a new drug," so now it is selling plasma "from donors who are younger than our patients."

Other "studies" include stem cell treatments for autistic children, with little, if any, benefits previously show in appropriate trials or described in respected journal articles.

This document is only available to subscribers. Please log in or purchase access.

Copyright © 2024 by Society of Corporate Compliance and Ethics (SCCE) & Health Care Compliance Association (HCCA). No claim to original US Government works. All rights reserved. Usage is governed under this website's Terms of Use.

Copyright © 2024 by Society of Corporate Compliance and Ethics (SCCE) & Health Care Compliance Association (HCCA). No claim to original US Government works. All rights reserved. Usage is governed under this website's Terms of Use.