per, it doesn't exist. We need to reconcile these divergent views.

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Clinical Research

The Policy Forum by Ralph Snyderman and Edward W. Holmes, "Oversight mechanisms for clinical research" (*Science*'s Compass, 28 Jan., p. 595), is a positive addition to the growing debate concerning the state of clinical research and the problems that have accompanied human experimentation over the years (*1*). Snyderman and Holmes correctly point out the complex array of duplicate regulations and the problems inherent in complying with multiple regulations and their interpretations. The Food and Drug Administration, Office for Protection from Research Risks (OPRR), and institutional review boards (IRBs) often offer their own interpretations of the regulations, and it may be difficult to discern how they envision specific regulations to be implemented. There are additional issues that were not elucidated by Snyderman and Holmes, yet are central to the field of regulation and proper conduct of clinical investigation.

For example, a major weakness in our efforts to protect patients from the risks inherent in participation in clinical trials is the informed consent process. No regulation, however detailed, will improve this process until potential participants are fully informed of what they are volunteering for, and until methods for improving the entire process are developed and studied. Emphasis on the informed consent form, and not on the process of continuing education of study participants in the nature of the study and their role in it, will result in continued focus on a piece of paper, to the detriment of establishing true informed consent.

Another problem is that the IRB is not just another university or hospital committee. The IRB is mandated by law to perform certain specialized tasks. It has regulatory authority and must adhere to specific regulations. Members need to be educated in the proper conduct of their work, and this has been woefully inadequate (*2*). Sufficient resources need to be provided to the IRB (*2*), and members need to realize that the activities of an IRB member differ from those of members of other committees. The recent OPRR actions against the IRBs of several respected academic medical centers (*3*) support the recognition of the IRB as a special activity in the medical center and university.

Snyderman and Holmes identify "ethics of physicians being remunerated by pharmaceutical companies" as an important conflict of interest. However, proper conduct of clinical investigation requires time and effort, for which investigators should be compensated. Moreover, such compensation in the academic setting invariably goes to the investigator's section or department and not to his or her personal bank account. The conflict inherent in institutional faculty reviewing grants that may deliver millions of dollars of support, not to mention the accompanying prestige, to the institution that employs the members of the IRB is another conflict that needs to be addressed.

Finally, the stress inherent in a physician functioning as both a health care provider and a principal investigator of a clinical study has been acknowledged (*4*), yet no satisfactory resolution has been proposed. The two roles are irreconcilable, because the aims of each of these positions are in direct conflict. Creative solutions that incorporate sufficient safeguards for human rights and participant protection are urgently needed.

As clinical investigation engages more of the general population and a significant number of those in the health care system, there is an urgency to more completely develop the dialogue within the medical community and the population at large. Our efforts to ensure ethical conduct of experimentation with humans need to catch up with the incredible advances in science.

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CORRECTIONS AND CLARIFICATIONS

Letter: "Luzia is not alone" (*Science*'s Compass, 11 Feb., p. 974). In two instances the word "million" was inadvertently added to human skeleton ages during editing. The oldest human skeleton found in the Americas dates from 11,000 to 11,500 years ago, and the 15 specimens referred to in the last paragraph date between 8500 and 11,500 years ago.