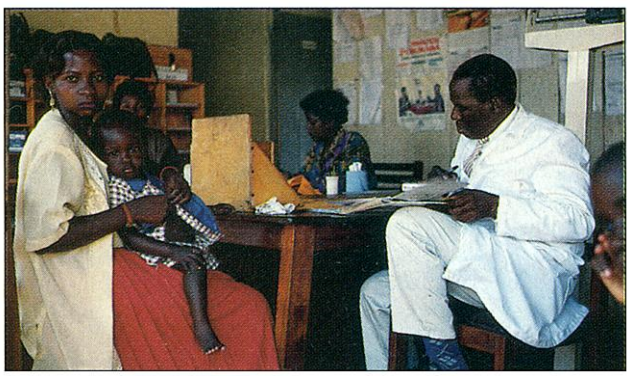
search and Development (LDRD) funds. Last year, Congress had slashed the decentralized accounts, which many labs use to seed promising research, after concerns that some labs were misusing the money (*Science*, 5 November 1999, p. 1064). But the new spending bill allows directors once again to channel up to 6% of their core budget to LDRD grants. At Livermore, that means a jump from $35 million to $52 million. "It's a big relief," says lab spokesperson Susan Houghton.

–DAVID MALAKOFF

CLINICAL TRIALS

Panel Proposes Rules For Research Abroad

Before scientists begin a clinical study in the developing world, they should make sure any successful treatment that results will be made available not just to trial participants but to the whole host country, according to a controversial recommendation from a presidential panel. The U.S. National Bioethics Advisory Commission (NBAC) on 29 September released draft guidelines* that would set this high bar for clinical research in foreign countries. NBAC took up the issue last year in response to controversies over placebo-controlled trials involving HIV-infected mothers and international trials of AIDS vaccines.



New criteria. Studying nevirapine, a drug that prevents mother-to-child HIV transmission, in Kampala, Uganda.

Ethicists and researchers have vigorously debated whether researchers from a wealthy country like the United States must provide the same standard of care to research subjects in foreign countries—even if they would otherwise have no access to such treatment. In the best known example, researchers came under attack for conducting studies that proved the effectiveness of a simple and cheap AZT therapy for HIV-infected pregnant women (*Science*, 27 February 1998, p. 1299). Some women received a placebo, even though AZT is effective and is standard treatment in the United States. The researchers considered this reasonable because the standard course of AZT is too expensive for most poor countries.

The NBAC panel acknowledges such dilemmas. The report says that researchers and sponsors should provide "established, effective treatment" to all study participants, whether or not it would usually be available. However, the guidelines allow exceptions. For example, if a researcher can explain to an ethical review board why providing treatment would render a study irrelevant to the host country, then a trial without standard therapy might be acceptable. Offering such flexibility is a step in the right direction, says physician and bioethicist Robert Levine of Yale University School of Medicine. The requirement that all studies provide the best known treatment is "out of touch with the realities."

The NBAC report would permit some flexibility on informed consent as well. Researchers have complained that a traditional U.S. requirement—that each volunteer must sign a written document that outlines possible risks and benefits—is meaningless in countries where few people read or write. Although individual informed consent is required, the report says, a written document may not be. In places where a request to sign a document may seem threatening, for example, ethics review boards could allow researchers to document verbal consent of some kind.

The panel's most controversial recommendation involves obligations both before and after a study takes place. Before work begins, the recommendations state, researchers and sponsors should explain how treatments that prove successful will be made available both to research participants and to the country as a whole. Although the principle is laudable, the guideline expects too much of researchers, says Francis Crawley of the European Forum for Good Clinical Practice in Brussels, Belgium. "These are enormously complex discussions," he says. "Often there is no way [a researcher] can tell how a treatment might be made available." Bioethicist Norman Fost of the University of Wisconsin, Madison, thinks such a requirement could slow down or prevent important trials. In the developing world, he says, participation in a trial is often a benefit, not a burden. In addition, he says, "there's no moral basis for the claim that individuals who aren't in the study are owed something."

NBAC will accept public comments on the draft through 13 November, says executive director Eric Meslin, and it aims to approve final guidelines in December.

–GRETCHEN VOGEL

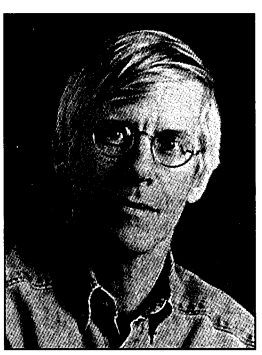
ETHICS

Epidemiologists Wary of Opening Up Their Data

ATLANTA—Epidemiologists, like journalists, have a tradition of protecting their sources, but now they're confronting demands that they open their files to the public. At the annual meeting of the American College of Epidemiology (ACE) here on 26 September, members debated how to comply with new federal rules that mandate data sharing. Finding a way to do that without jeopardizing subjects' privacy will be hard, many said. Indeed, some researchers warned that privacy concerns are already making it difficult, if not impossible, to recruit participants for some studies. Despite the sometimes heated discussions, Jonathan Samet, chair of epidemiology at Johns Hopkins University in Baltimore, Maryland, reminded the crowd that in reality, "there isn't a debate. There's a law."

Samet, ACE's president, was referring to a rule known as the "Shelby amendment," which passed Congress in 1998. As interpreted by the Office of Management and Budget, it requires federally funded researchers to make available raw data that support results that have been used "by the federal government in developing policy or rules" (*Science*, 12 February 1999, p. 914). Some researchers say that the best way to deal with potential requests for data is to routinely deposit material in an archive that can be opened to the public when results are published. But this idea was not popular in Atlanta, where, by a show of hands, the audience voted overwhelmingly against it.

Indeed, defenders of the public archive idea were hard to come by, says debate orga-



Data release. Christine Bachrach *(left)* argued for public archiving; Jonathan Samet warned of hard lessons ahead.

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* Available at http://bioethics.gov