

he thinks people may have been in Australia long before the Mungo 3 man lived. "We do not know when humans first arrived, and this date on Mungo 3 is an important way of saying that."

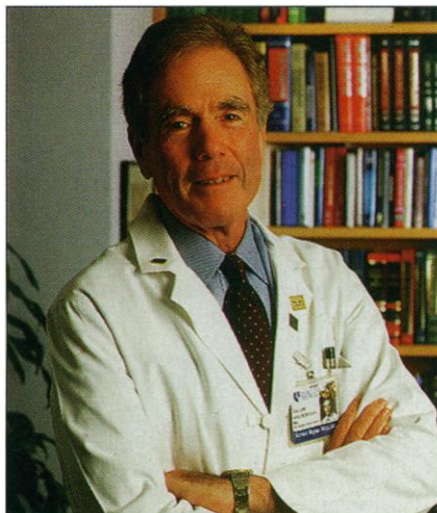
—CARL ZIMMER

Carl Zimmer is the author of *At the Water's Edge*.

## CLINICAL RESEARCH

### Shutdown of Research At Duke Sends a Message

Last week was a roller coaster for Joanne Kurtzberg, a transplant researcher at Duke University's Medical Center in Durham, North Carolina. First she heard—from a nurse—that her study using placental cord blood as a stem cell source had been suspended. "One of the OB-GYN doctors had come down the hall and said we couldn't consent any more patients," Kurtzberg recalls. Most other clinical researchers at Duke



**Under scrutiny.** Snyderman plans to re-review hundreds of clinical trials.

received similar shocks as word raced around the building that the Office for Protection from Research Risks (OPRR)—a federal watchdog agency that is part of the National Institutes of Health in Bethesda, Maryland—had lifted the center's authority to do federally funded research. Four days later, the immediate crisis eased when OPRR lifted the sanctions.

But the reverberations will continue at Duke and elsewhere. OPRR had suspended the Duke studies after months of urging administrators to correct "serious deficiencies" in procedures for monitoring consent and keeping records. Although the agency has now accepted a reform plan put together by chancellor for health affairs Ralph Snyderman and medical school dean Edward Holmes, OPRR director Gary Ellis notes that Duke still needs to re-review many pro-

jects for compliance with human subjects protection rules. That could take weeks. And with this action—the second shutdown of research at a major clinical center it has ordered in as many months—OPRR has put every federally funded U.S. research institution on notice that its right to conduct clinical research could be summarily yanked.

As though to underline the warning, the President's National Bioethics Advisory Commission (NBAC) also released a statement last week identifying defects in the U.S. system of protecting human research subjects. In a 4 May letter to President Clinton, NBAC chair Harold Shapiro describes gaps in enforcement and promises to deliver a "comprehensive report" in a few months loaded with recommendations for improvement.

OPRR isn't waiting for such advice. In focusing on Duke, it has targeted one of the nation's top biomedical centers. Duke has been aggressively adding staff and facilities—including a special center for industry-funded studies called the Duke Clinical Research Institute—to increase the number of clinical trials it manages. It now has 2000 in its portfolio, says medical center spokesperson Nancy Jensen. In December, OPRR sent nine experts to take a close look at Duke's procedures for monitoring the welfare of patients participating in this burgeoning research enterprise. After poring over records and interviewing staff, the team found no evidence that any patients had been harmed but concluded that the institution needed to tighten its practices.

Immediately after the site visit, OPRR sent a six-page letter to Snyderman listing 22 problems and asking for major changes. In February, OPRR followed up with another letter, warning that fixes offered by Duke were "unsatisfactory." For example, OPRR had asked that members of a panel that clears proposed experiments—the Institutional Review Board (IRB)—be better educated on relevant federal law. Duke responded by suggesting that it might invite IRB members to an annual lecture and brief them on useful Internet sites. Not good enough, OPRR said. Instead, it called for "provisions to ensure that all IRB members periodically receive interactive or didactic training from expert consultants working in the field of human subject protection."

OPRR also faulted Duke for allowing administrators to serve in a conflicted role as voting members of the IRB, for keeping sketchy records, and for failing to staff the IRB adequately. Duke responded in April and May with more suggestions, but OPRR officials again failed them. On 10 May, citing a "lack of progress" and a "failure of leadership," OPRR halted clinical trials.

Snyderman, who says he had no inkling

OPRR was considering such drastic action, estimates that "hundreds" of trials were affected. Some clinicians were faced with the possibility that they would have to delay enrolling patients while their projects were re-reviewed. Kurtzberg, for example, learned that her study offering experimental therapy to infants with a neurological disorder may fall in that category. She's still not sure when enrollment will resume.

Duke's medical chiefs may take comfort in knowing that they are not alone. Last month, OPRR shut down the Veterans Administration hospital in Los Angeles for similar reasons, and 5 months earlier, the Rush Presbyterian St. Luke's Medical Center in Chicago (*Science*, 2 April, p. 18, and 6 November 1998, p. 1035). Asked if this signals an escalation in enforcement, perhaps in response to congressional urging, OPRR chief Ellis responded, "that's for others to comment on." However, he noted that at a hearing last year, a prominent congressman called OPRR's enforcement efforts "pathetic" and "absurd." Ellis added, "With intense interest in human studies from Congress, the President's National Bioethics Advisory Commission, and advocacy groups, this is no time for dawdling."

—ELIOT MARSHALL

## PLANETARY SCIENCE

### Space Rock Hints at Early Asteroid Furnace

Long before Earth or any other planet had formed around the sun, a vast cloud of dust began to coalesce into asteroids. Most of the drifting chunks were the kind of stone-cold rubble that Han Solo had to weave through in his clunky old spaceship in *Star Wars*, but others were big enough, and hot enough, to ooze lava. For decades, planetary scientists had suspected that radioactive decay stoked the furnace of these hefty asteroids, some of which later merged into planets. But the embers that would identify the heat source have long since died out.

Now comes the first hard evidence of what melted large asteroids in the early solar system. On page 1348, a team led by planetary scientist Gopalan Srinivasan of the Physical Research Laboratory in Ahmedabad, India, reports that a 4.57-billion-year-old meteorite—a fragment of an asteroid that developed a molten interior and crust in the early days of the solar system—bears the unmistakable signs of a radioactive heat source. The rock once contained enough of the radioactive isotope aluminum-26 to have melted. "They've got the smoking gun," says Stuart Weidenschilling of the Planetary Science Institute in Tucson, Arizona.

Thought to have been blown into our so-