

Probe Opens on Study Tied to Johns Hopkins

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BALTIMORE, Aug. 22 -- The federal agency that monitors research involving human subjects has opened an investigation into a lead paint study overseen by Johns Hopkins University and conducted by its affiliate, the Kennedy Krieger Institute, in the mid-1990s.

The same agency recently halted for five days all federally funded medical research at Johns Hopkins involving human subjects after a similar investigation into a Hopkins asthma study that resulted in the death of a healthy volunteer.

The lead-paint study, which recruited healthy children and their families to live in Baltimore houses with varying amounts of lead contamination, was denounced by the Maryland Court of Appeals in an opinion issued last week. Six of the seven judges who heard the case likened the study to an infamous 1940s Tuskegee, Ala., study that withheld treatment from black men infected with syphilis.

The investigation by the Office for Human Research Protections -- an agency of the U.S. Department of Health and Human Services -- was launched before the court's opinion was issued, although federal officials would not say exactly when it began.

Johns Hopkins and its affiliates, including Kennedy Krieger, have permission to conduct experiments involving human subjects under a blanket order approved by the Office for Human Research Protections that will expire in October 2003, said Bill Hall, a Health and Human Services spokesman.

Since 1990, 29 percent of the 700 investigations conducted by the Office for Human Research Protections have led to temporary or permanent bans on studies involving human subjects, Hall said. Johns Hopkins receives more federal research dollars than any other medical school in the country.

Johns Hopkins officials said they were contacted by the Office for Human Research Protections about the investigation for the first time late today. A faxed letter asked Johns Hopkins to review one aspect of the lead paint study, said spokeswoman Joann Rodgers.

Rodgers declined to say what aspect of the lead paint study was mentioned in the letter or to divulge other details about its contents.

A panel of Johns Hopkins faculty members, known as an institutional review board, oversaw the Kennedy Krieger lead paint study. Maryland Court of Appeals Judge Dale R. Cathell, who wrote last week's scathing opinion, said the board instructed Kennedy Krieger researchers to write consent forms for study participants that skirted federal regulations requiring disclosure about risks.

The Court of Appeals ruling ordered trials to be held in lawsuits filed against Kennedy Krieger by two women, Viola Hughes and Catina Higgins, whose children were involved in the study. Hughes's daughter now suffers from learning disabilities and cognitive impairments, both of which are often associated with lead poisoning, according to their attorney. Higgins says researchers withheld tests results that showed high levels of lead contamination from her.

Kennedy Krieger recruited 108 families for the study, which was designed to find cheaper ways to reduce lead contamination so that landlords in poor areas here would not abandon their property.

Kennedy Krieger is a major institution in the study of lead paint abatement. Marc Farfel, who conducted the study, said today that it identified more effective ways to remove lead hazards and prompted legislation forcing landlords to remove those hazards.

Farfel and Kennedy Krieger Chief Executive Gary W. Goldstein said they were concerned about the wording of Cathell's opinion and saw no parallels between their study and the Tuskegee experiments.

"It's very inflammatory, because there is a constituency out there that is very worried . . . about experiments on minority groups," Goldstein said. He declined to identify other participants in the study, which was conducted in East Baltimore neighborhoods with high concentrations of poor and minority residents.

Since the court issued its ruling regarding the lead paint study, the institute has continued its research with two studies related to lead paint. In one, half of the participants -- children ages 1 to 8 -- receive a drug known to reduce elevated levels of lead in the blood, while the other half receive a placebo, Goldstein said.

The other study, which is in the enrollment phase, will test whether zinc tablets reduce lead in the blood.

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