

HoustonChronicle.com

Looking for job security?

[HoustonChronicle.com](http://www.HoustonChronicle.com) -- <http://www.HoustonChronicle.com> | [Section: Local & State](#)

Sept. 20, 2000, 12:08PM

Some research at UTMB frozen

Federal investigation alleges inadequate patient protection

By LEIGH HOPPER
Copyright 2000 Houston Chronicle Medical Writer

Federal officials have ordered the University of Texas Medical Branch at Galveston to immediately halt some of its federally funded medical research until it corrects alleged lapses in protection for patients participating in clinical studies.

The restriction is the second placed on UTMB this year. In July, the Office for Human Research Protections ordered UTMB to suspend enrollment of prisoners in 195 medical studies.

UTMB officials said they would not know the number of suspended research projects until Thursday or Friday.

UTMB is scrambling this week to correct deficiencies cited by the federal agency, after it investigated during a visit to UTMB last week. The agency, a division of the Department of Health and Human Services which oversees patient safety in research, severely criticized UTMB for its informed consent procedures as well as its review process for research proposals.

The institution was caught off-guard by the agency's latest action.

"We didn't expect this level of response from them," said Dr. Cheryl Chanaud, director of UTMB's office of clinical trials. "We thought they would give us some guidance on what they would like to see changed. We are making every endeavor to meet their requirements."

The restrictions do not interfere with UTMB's federal funding for research.

In a Sept. 14 letter written after the site visit, the agency commended UTMB for its "enthusiastic and sincere commitment to the protection of human subjects."

But the letter went on for 10 more pages, outlining problems and shortcomings with UTMB's oversight committee on patient research. The committee, called an institutional review board, or IRB, is charged with ensuring research projects meet federal guidelines to protect patients. Additional guidelines apply when research involves prison inmates.

The agency reviewed IRB files for more than 50 research projects, and the minutes of review board meetings convened during the past three years. Of 25 research projects approved for the involvement of prisoners reviewed by the agency, it found problems with more than half of them.

Among the criticisms stated in the agency's letter:

- Some of the studies were not considered to offer "reasonable probability of improving the health or well-being of the subject" as required. The agency was concerned that some of the projects posed "greater than minimal risk" to subjects.
- The review board made decisions without sufficient information about patient enrollment procedures; according to minutes of its meetings and discussions with the review board's members and staff, "little substantive review takes place at convened meetings of the IRB."
- UTMB overstated the potential benefits and understated the risk of a particular project in its informed consent documents.
- The language used in informed consent documents frequently includes "complex language that would not be understandable to all subjects."
- UTMB does not routinely require informed consent documents in the native language of potential subjects who do not speak English.
- The current membership of the institutional review board appears to lack the diversity of race, gender and cultural backgrounds required under HHS regulations.

"OHRP is concerned that the deficiencies cited above may be indicative of an IRB overburdened by the large volume of research for which it has oversight responsibility," the letter stated. "It is OHRP's experience that such a large volume of human subjects research warrants more than one fully functional IRB."

The agency is requiring that UTMB provide a complete list of all suspended research projects by Sept. 28, and submit quarterly progress reports documenting implementation of required corrective actions. The first report is due Dec. 15.

Suspension of enrollment of prisoners required by the July 10 letter must remain in effect until the protocols have been re-reviewed and approved, the agency said.

In addition, the agency is recommending that UTMB appoint more than one prisoner or prisoner representative to the review board. The agency asked UTMB to submit by Oct. 15 a detailed description of the qualifications and background of any proposed prisoner representative.

UTMB has already installed one such representative, a member of the Texas Inmate Families Association, on its 37-member review board, which is composed of 32 UTMB faculty members, plus five community members.

The agency also recommends the use of independent monitors to observe the informed consent process for prisoners, as well as a formal, mandatory training program regarding ethical principles and requirements for research involving prisoners.