UNIVERSITY OF CINCINNATI
COLLEGE OF MEDICINE

MAILING ADDRESS
RADIOISOTOPE LABORATORY
CINCINNATI GENERAL HOSPITAL
CINCINNATI, OHIO 45229

February 16, 1972

Dr. Evelyn Hess
J-3
Cincinnati General Hospital

Dear Evelyn:

Certain of the activities of the Radioisotope Laboratory revolve around improved methods of preparation of radiopharmaceuticals where the chemistry of a particular preparation is changed. At each event such as this a new IND is submitted to the FDA.

The question in my mind is whether each change of this sort need be submitted to the Faculty Research Coomittee as a research project requiring signed informed consent. We have on several instances in the past sent you copies of the IND for your records.

Could you let me know whether the present procedure is adequate or whether it would be necessary to make each one of these preparations an entirely new event.

Sincerely,

Gene

Eugene L. Saenger, M.D.

ELS/ml

AMA FROWNS ON EMERGENCY HEALTH AS SPECIALTY, charges Dr. R.R. Hannas, who said that the Council on Medical Education "fails to recognize the need for guidelines for the necessary graduate training, and is obviously hung up on principles of in-depth and in-breadth specialization." Hannas told the Assn. for Hospital Medical Education meeting in Chicago Feb. 3 that "there will probably be many thousands of emergency physicians before this specialty is permitted to have the same standards and rewards enjoyed by specialties far less important to vast numbers of patients." He recalled that having family medicine recognized as a specialty took "an amazing number" of years and described the council's attitude as a "roadblock."

¶ Hannas listed seven steps in the development of emergency medicine as a specialty. The first was content definition, and he told the MDs assembled that the public was defining the specialty and that MDs are mistaken to ignore that development. The next two steps were graduate training programs and the medical school role. He suggested that hospitals establish residencies in emergency medicine -- "it will be a most popular residency," he said -- and that the schools produce graduates qualified for the residencies.

¶ The next step, he said, is establishing a certifying board -- "admittedly further down the road, but another inevitable." Preliminary work on the next step, examinations, already has begun, Hannas said, with work on self-evaluation and in-service examinations. The sixth step, continuing education, is already in process with three annual scientific assemblies, and training programs at Mass. General and Bohnemann. The final step is research into improving the delivery of emergency care.

Hannas said the American College of Emergency Physicians is growing by 100 members a month and now has 2,300. In addition to meeting patient and hospital needs, Hannas said, these emergency MDs are satisfying some new state laws that require the presence of an MD 24-hours a day in emergency depts.

NEW GUIDELINES ARE ABOUT PATIENT PROTECTION from invasion of privacy as well as physical risk by clinical researchers in a recently published policy report that expands on the 1966 regulation on human subjects. The report says that consent obtained for one experiment or for services may not be appropriate for another experiment and should be carefully reviewed. Strict care should be taken of patient anonymity in all experiments.

¶ The policy review touched only lightly upon the need for special review in the case of institutionalized, mentally ill, or pediatric patients or minority populations. Donald Chalkley, PhD, NIH grants management guard, told "The Blue Sheet" that NIH has recently become sensitive to additional considerations for special experimental populations, but more study is needed.

Chalkley said NIH encourages representatives of the special populations be included on the institutional review cmte. which supervises the project. Besides members of a minority community, this would mean inclusion of students or even prisoners on the boards reviewing research procedures at institutions.

¶ A final warning in the regs says that NIH will review any project about which an infringement of human rights is reported. If any irregularities are found, HEW will terminate support, even the regs. Termination on these grounds has never occurred, and Chalkley said it is not likely. HEW generally gives notice if it is dissatisfied and allows institutions to reorder their procedures. The regs and their explanation are available in The Institutional Guide to DHEW Policy on Policy on Protection of Human Subjects for 25 cents, from the Govt. Printing Office.

CINCINNATI U. RADIATION EXPERIMENTS ATTACKED BY FACULTY GROUP; AMERICAN COLLEGE OF RADIOLOGY REPORT A WHITEWASH, THEY ALLEGE

The controversy over Cincinnati U.'s whole-body radiation cancer treatment experiments, financed in part by the Dept. of Defense, was reheated with a report by the university's Junior Faculty Assn. that directly contradicts the favorable report by an American College of Radiology team ("The Blue Sheet," Jan. 5, RN-1). The new study charges that 21 of the 87 patients who participated in the experiments may have died from radiation injury, and that "the selection of patients and the radiation dose given them was at least partly tailored to the needs of the DOD project."

The Junior Faculty Assn. is composed of 50 untenured members of the faculty. The cmte. assigned to make the study was headed by Martha Stephens, an assistant English professor, and Henry Anna, assistant political science professor. No members of the cmte. are MDs, but the group claimed it had "extensive help" from the medical community.

> **Charging that "many patients in this project paid severely for their participation and often without even knowing they were part of an experiment," the report asked Cincinnati President Warren Bennis to stop the project and to cooperate in hearings planned by Sen. Edward Kennedy's Senate Health Subcmte. A spokesman for Kennedy said no hearing date had been set, pending completion of a General Accounting Office investigation that started last week.**

Bone marrow failure, induced by radiation, presents the greatest danger 25-40 days after exposure, the faculty report said. Its study showed that 14 subjects died within that period, and that seven others died within the first 20 days. The study quotes a 1966 report to DOD by MDs involved in the project that "severe hematologic depression was found in most patients who expired."

ACR Contributes To 'Deceptive Impression' That Nausea, Vomiting Only Adverse Effects of Irradiation

The ACR study cited the use of bone marrow transplants to ameliorate radiation effects and said the Cincinnati project had successfully used that procedure since 1969. The faculty cmte. criticized the ACR conclusion and "misleading statements" by project MDs concerning protection by bone marrow transplants. "Of the first 50 patients only two received transplants and neither was a clear success," the report said. One of those two died 28 days after irradiation.

Informed patient consent has never been adequately obtained, the faculty report charged. No consent forms were used at all during the first five years of the project, it said, and a short consent form initiated in 1965 made no mention of specific risks from radiation injury. The latest form, adopted in the spring of 1971, does list under "risks" a paragraph on bone marrow problems.

> **The faculty cmte. criticized the project team for not publishing any of their findings on whole or partial body radiation. "Is it conceivable that in an authentic cancer research study no results would be reported after 11 years and the radiation of 87 patients? If no pattern had emerged. . .would this in itself not have been worth communicating this to other cancer specialists?" the report asked.**

Dr. Henry Kaplan of Stanford, who headed the ACR team, was not available for comment on the faculty report, which had this to say about the ACR's investigation: "We are confident that this (ACR) report will not be taken seriously by anyone properly informed about this project. The ACR omits from their report the more damaging statistics on patient survival. . . .The ACR doctors contribute, in other words, to the deceptive impression that the main side effects from radiation were nausea and vomiting within the first few days."

CANCER EXPERIMENTS AT CINCINNATI CERTAIN TO BE CHANGED, PERHAPS DROPPED, AS RESULT OF SERIES OF INVESTIGATIONS; MORE ARE TO COME

Cincinnati U.'s beleaguered whole-body radiation cancer treatment program is nearly certain to be modified, if not discontinued entirely, in the aftermath of a series of reports and investigations still going on. The possibility exists that Sen. Kennedy (D-Mass.) will develop the controversy into an attack on the concept of peer review of medical practices. And the university could still find itself in hot water with NIH, depending on the outcome of the investigation by the General Accounting Office (GAO).

> ● The controversy carries the potential for a highly emotional flareup involving use of welfare patients as subjects for research of questionable value in a program financed in part by the military. The only significant findings to date are those considered of military value by the Defense Dept. It's a situation made to order for aggressive leaders of minority, welfare and anti-military groups. Medical schools and other research institutions which ignore these implications may be heading for serious trouble, to the detriment of all biomedical research.

One of the three reports on the program gave it a clean bill of health and recommended it be continued, another condemned it and demanded it be terminated; and a third suggested it be continued with modifications. Full texts of the favorable report, by the American College of Radiology, and the critical one, by the university's Junior Faculty Assn., appear in this issue of "The Blue Sheet," starting on p. 5-21. The text of the report recommending changes in the study, made by a medical school faculty cmte., hasn't been made public, although a summary of its conclusions was announced Feb. 2).

NIH Ethics Watchdog "Not Overwhelmed" By Critical Junior Faculty Assn. Report, He Says

The GAO investigation, undertaken at Kennedy's request, will be completed about March 1, a spokesman for the senator said. Kennedy will decide then whether or not to schedule hearings on the controversy by his Senate health subcmte.

> A GAO report concluding that patient welfare hadn't been adequately guarded would give Kennedy ammunition for an attack on peer review as a means of care quality control. Key members of his staff are known to feel that a quality control process in which only MDs review the work of other MDs cannot work. Both reports that endorsed patient welfare aspects of the whole-body radiation experiments were written by colleagues of the project director, Dr. Eugene Saenger.

Donald Chalkley, NIH's ethics "watchdog," has followed the controversy closely since its inception. Chalkley said then that "If an institution is careless with one group of patients, it may be careless with others," and that the controversy raised the issue of confidence in an institution ("The Blue Sheet," Oct. 27, p. 21). But he praised Cincinnati's record on other programs and said he would be "very much surprised" to find that the university's cancer experiments had deviated from NIH guidelines.

That was before the JFA made its report, in which it charged that patients never had been fully informed of risks involved and that evidence indicated as many as 24% of the subjects had died of radiation injury.

"I'm not overwhelmed by the JFA report," Chalkley told "The Blue Sheet." Who said those patients died of radiation injury?" He contended that dosages given the subjects were not enough to have hastened their deaths. Dosages up to 200 rads are not considered lethal, Chalkley said. The fact that 24% died during the time period following irradiation when radiation-induced bone marrow suppression was at its peak was not conclusive evidence, he insisted. "I haven't seen any pathology reports, and neither did the JFA cmte., according to the report."