

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
FOURTH DIVISION
4-94-CV-448**

James A. Halikas, M.D.

versus

The University of Minnesota; the Institutional Review Board - Human Subjects Committee, of the University of Minnesota and its members: Susan A. Barry [sic], M.D., Christopher C. Kuni, M.D., Richard W. Bianco, David R.P. Guay, Pharm.D., Martin L. Gunderson, Ph.D., J.D., Dale E. Hammerschmidt, M.D., and Judith E. Reisman, Ph.D.

ORDER

This matter has been before the Court on a prior occasion. In May, 1994, plaintiff sought a preliminary injunction, which application was denied Halikas v. University of Minn., 856 F. Supp. 1331 (D. Minn. 1994). Since that ruling, the parties have engaged in discovery, and the matter is approaching trial.

Defendants seek summary judgment, pursuant to Rule 56 of the Federal Rules of Civil Procedure ("Fed.R.Civ.P."). They ask the Court to dismiss plaintiff's remaining claims, which assert violations of due process. Defendants deny they have deprived plaintiff of any protected property, liberty interests, or substantive due process rights. Defendants further assert that the plaintiff received all the process he was due. Plaintiff, now appearing pro se, opposes the motion. The matter was argued for the second time on June 7, 1996.

I. Background

Plaintiff, James A. Halikas, is a tenured professor in the University of Minnesota Medical School's Department of Psychiatry. In March, 1992, Dr. Halikas applied to the University's Institutional Review Board ("IRB") for permission to conduct medical experiments on human subjects. The IRB is a medical research review body established to assure compliance with University and federal drug research standards. See 21 C.F.R. § 56.101 et seq.

Dr. Halikas received IRB approval and began his experiments in the summer of 1993. The experiments were designed to test the efficacy of the drug Gamma Hydroxybutyrate ("GHB") in curbing chemical dependence. Among his research subjects were a number of non-English-speaking Southeast Asian patients.

In August, 1993, the IRB received a letter questioning whether Dr. Halikas's GHB study patients had signed required informed consent forms. See Keane Aff., Exh. B. The letter also

claimed the experimental subjects had been denied the opportunity to select the standard forms of treatment. *Id.* Upon learning of the letter, a few days after its receipt by the IRB, Dr. Halikas voluntarily terminated his study. He informed the IRB of his decision on August 10, 1993.

On September 10, 1993, the University issued a press release stating that the IRB had begun investigating the GHB study. At the time the release was issued, the IRB had not formally voted to investigate Dr. Halikas's study. The IRB began to investigate the study on October 13, 1993, and suspended all of Dr. Halikas's human-subject research on November 12, 1993.

As part of its investigation, the IRB questioned a number of witnesses. Dr. Halikas was not present for these interviews. The IRB sent two letters to Dr. Halikas setting forth the IRB's concerns and requesting Dr. Halikas's response. On January 31, 1994, Dr. Halikas appeared before the IRB panel, accompanied by his lawyers, and testified for at least two hours. At this hearing, Dr. Halikas requested the chance to cross-examine the complainants and review the IRB's documents. The IRB denied these requests.

The IRB issued its conclusions on March 21, 1994, finding that Dr. Halikas failed to obtain prior written informed consent from the study's subjects. It further found that Dr. Halikas exploited [the] vulnerabilities of the research subjects by failing to adequately explain the experiment to opium-addicted patients with significant cultural differences and language barriers. Finally, the IRB found Dr. Halikas administered higher doses of GHB than the IRB-approved protocol allowed. At oral argument, Dr. Halikas directly acknowledged that his research subjects had not signed the consent forms. He stated that he knew this early in August, 1993. Neither Dr. Halikas's responsive pleadings nor his argument disputed the IRB's other findings.

Dr. Halikas filed the present action on May 18, 1994. In his remaining claims, he contends he is entitled to redress, pursuant to 42 U.S.C. § 1983, for violations of procedural and substantive due process.

II. Discussion

Summary judgment is appropriate if there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); Celotex Corp. v. Catrett, 477 U.S. 317, 322-323 (1986); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 246 (1986). The party opposing summary judgment may not rest upon the allegations set forth in its pleadings, but must produce significant probative evidence demonstrating a genuine issue for trial. *Anderson*, 477 U.S. at 248-49; see also Hartnagel v. Norman, 953 F. 2d 394, 395-96 (8th Cir. 1992). In reviewing the evidence, the Court must resolve all factual disputes in favor of the non-moving party. Radaszewski v. Telecom Corp., 981 F. 2d 305, 310 (8th Cir. 1992), cert. denied, 508 U.S. 908 (1993).

A. Procedural Due Process

Based on the uncontested facts in this case, the Court finds that Dr. Halikas received all the process he was due in the course of the University's IRB investigation. The IRB, a federally mandated body operating under the direction of the University, is guided in its investigations by the Code of Federal Regulations and the University of Minnesota General Assurance Agreement. Halikas, 856 F. Supp. at 1335. The Court finds the IRB sufficiently complied with both sets of regulations.

The University received the letter of complaint in August, 1993. By August 10, 1993, Dr. Halikas had voluntarily terminated the GHB study. It is clear, therefore, that Dr. Halikas had

personal knowledge of a problem in the GHB study within ten days after the complaint was lodged. He received a number of notices of the charges against him, was sent a copy of the letter that triggered the investigation, testified before the IRB panel for more than two hours, and was invited to submit written documents in support of his position.

As a preliminary matter, Dr. Halikas contends the IRB was required to comply with the investigative procedures set forth in the University's tenure code and hospital by-laws. The Court disagrees. The parties acknowledge that, to this date, the University has taken no action against Dr. Halikas under either the tenure code or the hospital by-laws. It is conceivable that proceedings under these sets of rules may be invoked in the future, but no such step has been taken at this time. As a result, procedural claims based on those rules are not ripe and are not before the Court. The issue before the Court is the IRB and its proceedings.

Dr. Halikas further contends the IRB was constitutionally required to allow confrontation and cross-examination of witnesses and a review of the IRB's documents. Dr. Halikas is wrong.

An IRB proceeding is not a federal criminal prosecution and need not be accompanied by the full panoply of criminal procedural rights. See Meleen v. Hazeldon Foundation, 740 F. Supp. 687, 692 (D. Minn. 1990), aff'd, 928 F. 2d 795 (8th Cir. 1991). Rather, as the Eighth Circuit Court of Appeals has determined in similar cases, the Constitution requires only that Dr. Halikas receive: (1) clear and actual notice of the charges against him; (2) notice of the names of those bringing the charges and the specific nature and factual basis for the charges; (3) a reasonable time and opportunity to respond; and (4) a hearing before an impartial board or tribunal. See Riggins v. Board of Regents of Univ. of Neb., 790 F. 2d 707, 712 (8th Cir. 1985); King v. University of Minn., 774 F. 2d 224, 228 (8th Cir. 1985), cert. denied, 475 U.S. 1095 (1986).

There is no dispute that the first three Riggins factors have been satisfied. With respect to the fourth factor, Dr. Halikas asserts the IRB panel was not impartial. He bases his claim of panel prejudice on his assertion that certain members of the IRB panel interviewed witnesses or investigated the complaint. Here again, Dr. Halikas confuses administrative proceedings with the panoply of rights accorded a defendant in a criminal trial. The fact that an administrative panel member conducted interviews or sought information concerning a charge does not establish partiality or bias.¹ See Withrow v. Larkin, 421 U.S. 35, 47-48 (1975). Even assuming that the facts are as he asserts, Dr. Halikas offers nothing beyond his bare belief that the IRB panel was biased. He has made no evidentiary showing to compel a trial on this issue. See Anderson, 477 U.S. at 248-49. Accordingly, his procedural due process claim must be dismissed.

B. Substantive Due Process

Having found no procedural due process violation, the Court determines that any substantive due process claim must fail as well. As the Eighth Circuit has made clear, the right to substantive due process "is no greater than the right to procedural due process." See Weimer v. Amen, 870 F. 2d 1400, 1405 (8th Cir. 1989). Further, the Court finds Dr. Halikas is unable to show that any of the interests traditionally protected by substantive due process are [sic] implicated here. Substantive due process protection generally extends to matters such as "marriage, family, procreation, and the right to bodily integrity." Albright v. Oliver, 510 U.S.

¹ Indeed, under the civil or code law systems, the party in charge of an investigation and the person who brings the charge is the magistrate who conducts the trial. While no such facts have been asserted here, the Court cannot consider such a system, per se, unfair or [im]partial.

266 (1994). There is no substantive due process right to conduct human-subject research, nor would the claimed right extend to a bar against dissemination of an IRB investigation's results.

Finally, the Court determines that, even if substantive due process protections applied, Dr. Halikas cannot show that the IRB's and the University's actions were so egregious that he is entitled to relief. A plaintiff cannot prevail on a substantive due process claim unless he can show that the defendant's actions were "truly irrational." Chesterfield Dev. Corp. v. City of Chesterfield, 963 F. 2d 1102, 1104 (8th Cir. 1992). Here, the IRB acted, as its federal mandate requires, to protect the interests of human subjects of Dr. Halikas's study. See 21 C.F.R. §§56.103 and 56.113. Such actions are not irrational. See Halikas, 856 F. Supp. at 1336. Thus the Court determines that it must dismiss Dr. Halikas's substantive due process claim.

Accordingly. **IT IS ORDERED** that:

Defendants' motion for summary judgment is granted. This matter is dismissed with prejudice.

LET JUDGMENT BE ENTERED ACCORDINGLY

Dated: July 9th, 1996

James M. Rosenbaum
United States District Judge