

1
Winters

Application for a Medical Research Project

Colonel Svc

Judge Advocate

14 September 65
Mrs. Duerson/ain/67142

1. This office informally staffed the proposed research experiment with The Judge Advocate office of the Research and Development Command and concurs in attached opinion.

2. The proposed research involving human subjects would be objectionable as a violation of the Human Experimentation Code of Ethics as contained in the Declaration of Helsinki. Reference is made specifically to paragraph III, 3a and 3b of the Code of Ethics of the World Medical Association. The following is a quotation from inclosed statement by Medical Research Council as reported in the 18 July 1964 British Medical Journal: "In the strict view of the law parents and guardians of minors cannot give consent on their behalf to any procedures which are of no particular benefit to them and which may carry some risk of harm".

3. An official of the Washington D.C. office of the American Medical Association informed this office that the American Medical Association has taken no official position on the Declaration of Helsinki but that it is being studied. The Judicial Council of the 1946 House of Delegates of the AMA set forth the requirement that the voluntary consent of the person be obtained in all clinical research involving human experimentation.

2 Incl

1. JA R&D
Opinion

2. ~~Winters~~

MERLE C. RIDGOUT, JR
Colonel, JAGC
Judge Advocate

SGM

SARAH G. DUERSON
Asst Chief, Legal Office

Telephone conversation between Dr. Otis L. Anderson, Assistant Manager, Washington Office, AMA and Mrs. Duerson, 10 Sept 65.

HEADQUARTERS
US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
Washington, D. C. 20315

MEDDH-JA

20 August 1965

MEMORANDUM FOR: JUDGE ADVOCATE, OTSG

SUBJECT: Feto-Placental Blood Volume Experiment

1. Reference is made to the informal request of Mrs. Sarah Duerson of your office for an opinion with regard to the proposed research described in the attached file.

2. An examination of the subject proposal indicates that the procedure would be of no therapeutic benefit to the infant. On the contrary, there is expert medical opinion that the test would expose the infant to certain risks to which it would not otherwise be exposed. Although, it appears that these risks might be minimal, by no stretch of the imagination could these procedures be termed of benefit to the infant within the meaning of subparagraph 3c, AR 70-25, 26 March 1962. Under paragraph 6 of the cited AR, therefore, the proposal must be submitted to the Chief of Research and Development for approval.

3. The Chief of Research and Development has taken the position that the use of minors in research conducted by Department of the Army personnel is not acceptable since minors are legally incapable of volunteering and further that consent of the parents is not considered as free consent within the scope of AR 70-25. The Office of The Judge Advocate General has concurred in this decision.

4. For the reasons stated above it is the opinion of this office that the proposed research is legally objectionable insofar as it involves the use of human volunteers. There is, of course, no objection to the conduct of animal tests as indicated in the protocol.

Incl
File on subj.


J. B. CARRICK, JR.
Major, JAGC
Judge Advocate

Application for a Medical Research Project

MEMO-CR

Asst Ch Surgical Consul

Ch Radiol Consul

**12 Aug 65
Col Baker/pl/62395**

1. Recommended approval of the animal section of the basic proposal.

2. The estimated radiation exposure appears to be on the safe side; 30 millirads is probably high. This dose is probably safe, but the possibility of its producing leucosis at some future date cannot be completely ruled out. Detrimental genetic effect is also a remote possibility. The hazards enumerated by the Pediatric Consultant are greater than those due to radiation.

**ALBERT J. BAKER
Colonel, MC**

**1 Encl
File**

**Submission of Total
Fetal-Placental Blood Volume
(See Proj)**