

RECORDS SERIES TITLE	1961-72
COMMITTEE ON HUMAN EXPERIMENTATION RECORDS	
ACCESSION NO.	AR 86-23
FILE CODE NO.	
CARTON NO.	1 of 1
FOLDER NAME	Comm. Human Experiment: Reports, correspondence, memos
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1961-72-23-1

August 7, 1961

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Vice Provost Fleming  
260-S  
San Francisco Campus

Dear Bill:

I have been advised by Dr. Pettitt, of Vice President Corley's Staff, that the attached material will be submitted for approval by The Regents at their August 16th meeting due to the fact that it involves the sensitive subject of Human Volunteers. Approval is, however, expected to be routine.

You will be interested in the information which we obtained from Karl Meyer indicating the background of the request on the part of the Surgeon General for the addition of this section to Karl's work in the field of Immunization of Man Against Plague which as you know, has been going on for over ten years. Karl advises that he has been using human volunteers from the State of California, Department of Corrections Medical Facility at Vacaville, and that other investigators in this field have been doing likewise all over the country. Previously, no standards have been developed and it was felt in several quarters that some should be. Accordingly, the Army asked Karl and others to serve on a committee to develop acceptable standards with this result.

Since I understand you will be attending the Regents Meeting to represent this campus if necessary, Naomi asked that I forward you this information.

Sincerely yours,

Stanley C. Bateaux  
Business Manager

SCB:lp  
(dictated but not read)

cc: Provost Saunders  
Karl Meyer P.S.

In addition to the above information, I should advise you that Article 34 has been approved by the General Counsel of the University with a minor change in that they have asked that the Article be modified from its completely general nature to specifically include only those rules contained in Article 34 by the insertion of the two words "following enumerated" in the first sentence which will now read in part, "The following enumerated Principles, Policies, and Rules---." Vice President Corley Office will proceed to negotiate this change and it is my opinion that it will be completely acceptable to the Surgeon General.

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34 The Principles, Policies and Rules of The Surgeon General, Department of the Army, relating to the use of Human Volunteers in Medical Research are incorporated in and made a part of this contract:

1. The voluntary consent of the human subject is essential. This means that the person concerned:
  - a. Should have legal capacity to give consent.
  - b. Should be so situated as to be able to exercise free power of choice, without intervention of force, fraud, deceit, duress, over-reaching, or other form of constraint or coercion.
  - c. Should have sufficient knowledge and understanding of the experiment to enable him to make an enlightened decision, on the basis of explanation given to him as specified below:
  - d. Should state his consent in writing, signed in the presence of at least one witness who shall attest to such signature in writing.
2. Each individual who initiates, directs or engages in the experiment has a personal duty and responsibility for ascertaining the quality of the volunteer's consent.
3. Before the acceptance of consent of the volunteer, he must be given adequate explanation. He should be informed of the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.
4. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other means of study, and not random and unnecessary in nature.
5. The number of volunteers used must be kept at a minimum consistent with the requirement of a fruitful experiment for the good of society.
6. In order that the anticipated results will justify doing the experiment, it (the experiment) should be designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study.
7. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
8. No experiment should be conducted where there is a prior reason to believe that death or disabling injury will occur.
9. The degree of risk to the volunteer should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
10. The experiment should be conducted only by scientifically qualified persons (including an adequately trained physician) who shall be required to exercise the highest degree of skill and care throughout the experiment. Competent consultants should be available on short notice in this connection.

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Article 34 continued

11. Adequate preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death. This includes hospitalization and medical treatment as may be required.

12. The human volunteer subject should be at liberty to bring the experiment to an end if he feels that it is impossible for him to continue under the test.

13. The scientist or physician in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgement required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

14. Established policy prohibits the use of prisoners of war in human experimentation. They will not be used under any circumstances.

15. Agents used in research must have the following limiting characteristics;

- a. Controllable lethality
- b. No serious chronicity anticipated
- c. Effective therapy available
- d. Adequate background of animal experimentation.

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