

Attachments 1
2 pages

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March 2, 1962

Dr. Joseph W. Gardella
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Dear Joe:

You have asked for comments on Criticisms of "Principles, Policies and Rules of the Surgeon General, Department of the Army, relating to the use of Human Volunteers in Medical Research Contracts awarded by the Army".

The most difficult problem of all is not dealt with either in the Army's code or in any remarks made concerning the subject. I refer to the question of experimentation in one subject (patient) which cannot conceivably be for his benefit but is for the benefit of patients in general. Nearly all else is simple compared with this giant problem.

While one gains insight into troubling areas by reading the various codes which have been devised to lend dignity and safety to human experimentation, I believe it to be quite impossible to construct a useful code that will be sound, helpful and protective. If the code is sufficiently general it will have little or no value. If it is specific it will have to be of immense length, and yet will be unavoidably incomplete for no code could possibly apply to all or even most of the situations that will be encountered. Such a vast code would undoubtedly be restricting and crippling, and a mean instrument quickly used in support of law suits by the unscrupulous.

Most of the remarks I have to make concerning the manuscript you sent me turn on the point that as far as I am concerned valid consent cannot be obtained to experimental procedure when neither the experimenter nor the subject can possibly know what the risk involved may be. In nearly all serious cases no one knows the risk, nor can it be known. If it is not known of course it cannot be communicated.

On page 2, line 9: I would comment, in answer to your question, that there is no real problem here.

On page 2, line 21: I would comment, often not possible.

Page 2, line 26: I would insert my general comment again about the impossibility of valid consent in the absence of knowledge of risk.

Top of page 3: I would ask: Can a guardian soundly consent to something involving a risk or suffering for his charge which he, the guardian himself, will not have to undergo? I doubt this.

Dr. Joseph W. Gardella

2

March 3, 1962

Page 3, near the bottom: In my view one's own medical students are never fit subjects for investigation. The same applies to one's laboratory personnel. Subtle coercion is too easily possible

Page 3, line 4 from the bottom: "early parole ..." This may not be commensurate with the risk obtained.

Page 4, lines 1 and 2: Again, very often not known or not adequately communicable to the layman.

Page 4, line 14, following sentence ending "and trust": Nor in law either, as I understand it.

Page 4, line 6 from bottom, The quality of a volunteer's consent.... Once again, not valid if risk not known. Often the case.

Page 5, line 1: Comment - Often not possible.

Page 5, line 9: Comment - Connotes a utilitarianism not in accord with much basic investigation.

Page 5, middle of page: The phrase "for the good of society" certainly is in bad odor and should be avoided.

Very sincerely,

Henry K. Beecher, M.D.

HKB:rs

cc to Dr. Churchill