(DRAFT)

THE USE OF HUMAN EXPERIMENTAL SUBJECTS

The use of human beings as experimental subjects has been traditional in the fields of drug development and therapy. In fact, no final evaluation of the materials which have proved to be of benefit to mankind has ever been complete without human experimentation. Thus, it must be apparent that man cannot and should not be excluded from consideration as an experimental subject if information that is essential in the understanding of clinical disease and therapy is to be obtained.

Although a tremendous amount of information concerning the effects of industrial materials is obtainable from laboratory animals, an estimate of the safe concentrations of these substances must, of necessity, involve the study of human subjects. Therefore, in any consideration of safe limits, man's reactions must be observed and understood. For these reasons it is not only desirable but essential that the use of human experimental subjects be an important sequel to animal investigations. This concept has been expressed well by Ladimer who stated: "Human beings represent both a sacred and valuable resource for medical research when properly employed at the correct scientific stage."

Despite these considerations, however, the employment of human subjects has raised questions that are both practical

and philosophical and, therefore, difficult to resolve. The complex character of the issues that are involved and misunderstandings on the part of persons who are concerned both directly and indirectly makes it necessary that a definite policy with regard to human experimentation be established in any institution where human experimental subjects are used to any degree whatsoever.

For these reasons, certain broad principles are outlined here. These principles take into consideration the motivation of the subject, the educational implications and the conflict with required studies (when medical or other students are concerned), financial remuneration, the protection of health, and the moral and legal responsibilities of the investigator, the sponsor and the institution.

General Policy

1. Voluntary consent of the subject is absolutely essential. Consent must be based on knowledge and understanding of the elements of the study and awareness of possible consequences. This signifies 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.

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. The experiment should be such as to promise fruitful results for the good of society, unprocurable by other means of study, and not random and unnecessary in nature.

3. The experiment should be designed and based upon prior experiments on animals, if such experiments are capable of revealing any useful information, and a knowledge of the natural history of the disease or problem, and upon any other pertinent data, so that anticipated results may justify the action that has been taken.

4. The experiment should be conducted so that there will be no unnecessary physical or mental suffering.

5. No experiment shall be undertaken when there is reason to believe that death or disability may occur.

6. There should be preparation and adequate facilities to protect the subject against even the remote possibility of injury, disability or death.

7. The subject should be permitted to terminate the experiment

whenever he reaches a mental or physical state in which its continuation to him seems impossible or highly undesirable.

8. The investigator must be prepared to end the experiment, if he has reason to believe that its continuation is likely to result in injury, disability or death.

9. The experiment should be conducted only by scientifically qualified persons, including a physician, whose authority to discontinue the experiment is unquestioned, and whose knowledge of the field of investigation is ample. The investigators shall be required to exercise the highest degree of skill and care throughout the experiment. In addition, competent consultants should be available on short notice.

10. Agents to be investigated must be limited to those that possess the following characteristics:

a. Controlled lethality.

b. Freedom from serious chronic or residual effects.

c. Effects amenable to effective therapy.

d. Adequately investigated with respect to anticipable effects by prior experiments on animals or on basis of critically appraised human experience.

11. All experiments in which human subjects are to be employed must be reviewed by a research committee before their initiation. This committee will examine the purpose of the experiment, the

theory or basis for the proposal, prior laboratory or animal data, reports on related investigations, suggested control measures, techniques for the appraisal of results, and precautions for the safety of the subjects. The foregoing must be presented to the committee in writing before their consent can be given. Finally, the prosecution of the experiment must be authorized in writing by the administrative authority of the research organization, as the Head of a department or the Director of a laboratory.

12. Clinical and laboratory findings of the investigation shall be presented to the research committee at appropriate intervals during the experiment and at its completion. In addition, the research committee may interview any or all of the subjects at its discretion.

13. The experiment may be terminated at any point by unanimous consent of the research committee.

14. The employment of students as experimental subjects will be permitted only when the written permission of the Dean of the College concerned has been obtained.

15. All human experimental subjects will be covered by appropriate and adequate insurance.

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