humane standards and effective research unobstructed by either antivivisectionists or self-righteous scientists.

A medical, veterinary, or pilot's license is bestowed only on those who have shown a capacity to assume important social and professional responsibilities. Obtaining a license is a milestone in any career. A fledgling investigator learns, in England, to scrutinize his experiments from a humane as well as a scientific standpoint. He will discuss his work and the humane requirements of the law with his professor, fellow workers, and the inspector, who is a respected professional colleague, not a bureaucratic foe. Unfortunately, comparable nationwide concern with humane standards is lacking in the American research community.

Both Visscher (11 Feb., p. 636) and Rohweder (18 Feb., p. 778) intimate that federal legislation such as the Clark-Cleveland bills "would delay or prevent scientific discovery" and cause "an incalculable number of our friends . . . [to] die sooner because discoveries come later." Similar extravagant remarks could with as much, and as little, truth be made about delays in processing federal grants or, indeed, about scientists' summer vacations.

Laboratory animals are vehicles of our purpose as we are vehicles of God's; it behooves a civilized nation to treat them with mercy.

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Medical Experimentation on Humans

The recent discussion by Elinor Langer (11 Feb., p. 663) brings into focus many of the unresolved problems connected with experimentation on human beings. Without referring directly to the questions involved in the New York case she describes, I should like to raise a point, the disregard of which could seriously impede the accumulation of useful medical data.

It is essential to differentiate between two types of human experimentation in terms of the risk-versus-benefit ratio from the standpoint of the patient. These two categories may be termed "observational" and "manipulative." In the first, the procedure applied to the patient, be it diagnostic or therapeutic, is one which would probably have been applied to that patient in a nonexperimental situation, the only difference being that observational techniques are added which monitor data resulting from the procedure. It is implied, of course, that the observational techniques do not in themselves pose any significant risk to the patient. The diagnostic or therapeutic procedure is assumed to be either a standard one, or a nonstandard one which promises to be of benefit to the patient. Certainly precedent for this is as old as medicine itself, and the ethical and legal questions would appear to be well covered by the established codes of ethics governing the patient-physician relationship. Each patient is a unique problem and in this sense an experiment; and, indeed, it would seem unethical not to gather as many data as possible from the situation. Fortunately, most human experimentation at this time is of this type, and the untapped wealth of information to be derived from the application of scientific observational and data-processing methods to the practice of medicine is enormous. The ethical questions here, then, seem to be clear and well tried.

In the second category, that of manipulative experimentation, the questions are not clear, precedents are lacking, and extensive discussion from the ethical, medical, and legal standpoints is essential. Manipulative human experimentation is defined as the application to a patient of a risk-posing procedure which cannot conceivably benefit him. It needs to be clearly stated that it is this type of experimentation that is of primary interest to the various groups purporting to represent the public in these questions. If we neglect this, we run the risk that the rigorous controls necessary in the manipulative type of experimentation may be applied helter-skelter to everything termed "human experimentation."

Since there is much information to be gained from the observational type of human experimentation, it is questionable whether any manipulative experimentation should be condoned until the ethical and legal issues are resolved.

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Having read the News and Comment headed "Human experimentation: New York verdict affirms patient's rights," I believe I understand the situation well enough to attempt to help lay committees develop a series of forms for obtaining patients' informed consent. I am working now on forms (see note) for our standard operations. After these have been accepted universally, it should be possible to develop standard forms for less and less standardized procedures as we learn new methods of treating diseases and congenital deformities which afflict human beings but which with our present limited knowledge cannot be effectively treated.

In fact, however, we may never need consents for performing any procedures, small or large, that are not already well established. When the two dozen or so bills in Congress against experimentation in living animals go through, and when we are prevented from attempting seemingly innocuous studies of cancer behavior in humans, as reported in the article, we may mark 1966 as the year in which all medical progress ceased. Thereafter and for the rest of time, we would need only 200 or so standard informed-consent forms to cover only the 200 or so presently standardized operations.

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Note

Proposed informed-consent form for hernia patient:

I, ..., being about to be subjected to a surgical operation said to be for repair of what my doctor thinks is a hernia (rupture or loss of belly stuff—intestines—out of the belly through a hole in the muscles), do hereby give said doctor permission to cut into me and do duly swear that I am giving my informed consent, based upon the following information:

Operative procedure is as follows: The doctor first cuts through the skin by a four-inch gash in the lower abdomen. He then slashes through the other things—fascia (a tough layer over the muscles) and layers of muscle—until he sees the cord (tube that brings the sperm from testicle to outside) with all its arteries and veins. The doctor then tears the hernia (thin sac of bowels and things) from the cord and ties off the sac with a string. He then pushes the testicle back into the scrotum and sews everything together, trying not to sew up the big arteries and veins that nourish the leg.

Possible complications are as follows:

1) Large artery may be cut and I may bleed to death.
2) Large vein may be cut and I may bleed to death.
3) Tube from testicle may be cut. I will then be sterile on that side.
4) Artery or veins to testicles may be cut—same result.
5) Opening around cord in muscles may be made too tight.
6) Clot may develop in these veins which will loosen when I get out of bed and hit my lungs, killing me.
7) Clot may develop in one or both legs which may cripple me, lead to loss of one or both legs, go to my lungs, or make my veins no good for life.
8) I may develop a horrible infection that may kill me.
9) The hernia may come back again after it has been operated on.
10) I may die from general anesthesia.
11) I may be paralyzed if spinal anesthesia is used.
12) If ether is used, it could explode inside me.
13) I may slip in hospital bathroom.

14) I may be run over going to the hospital.
15) The hospital may burn down.

I understand: the anatomy of the body, the pathology of the development of hernia, the surgical technique that will be used to repair the hernia, the physiology of wound healing, the dietetic chemistry of the foods that I must eat to cause healing, the chemistry of body repair, and the course which my physician will take in treating any of the complications that can occur as a sequela of repairing an otherwise simple hernia.

Patient

Lawyer for Patient

Lawyer for Doctor

Lawyer for Hospital

Lawyer for Anesthesiologist

Mother-in-Law

Notary Public

Date

Place

Data Collection and Systems Analysis

W. C. H. Prentice writes (Letters, 4 March) about the problems raised by the increasing tendency to collect data for their own sake, particularly by means of questionnaire surveys. The remedies he proposes deserve close attention, for they can be generalized to apply beyond the limited domain of such surveys. The problem that Prentice addresses is far more pervasive and serious than may be realized. Because of the ease with which data may now be collected and processed, in some technical, economic, political, and social fields we are almost being studied to death. Many of the studies serve to obscure rather than to illuminate the central issues to be examined for effective decision-making. In addition—and this is potentially more serious—many such data collection studies are being represented as valid systems analyses of complex engineering, economic, political, and social problems.

In recent years some notable successes have been achieved through the application of the "systems approach" to a range of national security problems. The points of view and the techniques developed in such predominantly military systems have just begun to be extended wholesale to nonmilitary government, commercial, and industrial sectors. Examples include the fields of communication, transportation, urban development, education, health, and water-resources development. In the next 5 to 10 years this trend will increase sharply.

Systems analysis can be a powerful tool for decision-making in which are involved major allocations of resources in complex situations characterized by considerable uncertainty. Its essential components include goal setting (objectives, requirements, constraints), postulation and evaluation of alternatives (modeling, simulation, cost-effectiveness), and data collection (historical surveys, description of environment, structuring of relationships). These components are circularly related in the sense that the process of decision-making involves *sequential* and *iterative* application of goal-setting, alternative generation and evaluation, and data collection at successively deeper levels of analysis. The interactions among these phases—together with considerable human judgment—yield adjustments that ultimately converge to a "best" decision. Representing as it does the application of the scientific method to practical problem-solving, systems analysis is as applicable to problems involving personal choices as to problems involving the selection of an anti-missile missile system.

The basic point is that, in any of these applications, any data collection must be considered an integral part of the systems-analysis process. When this precept is ignored, considerable misplaced effort will result. These difficulties will increase as the complexity of the systems increase, for few limits can then be placed on the quantity of data that might be pertinent.

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Statistical Method

In reading the Reports in *Science* during the last quarter of 1965, I noted 16 in which statistical procedures were employed to the extent of making statements about "significance" or citing *P* values. (This count did not include reports giving means, standard deviations, or standard errors merely as summary values.) In eight of these reports I found errors in statistical method resulting from failure to understand the following:

1) The analysis of variance must be compatible with the experimental design described.

2) With regard to regression: (i) The correlation coefficient cannot "validate" a regression. (ii) The square of the correlation coefficient does not "demon-