The Welfare Department was unable to document that obtained consent of patients or relatives in a number of these tests.

There are nearly 4,000 persons in the city's welfare institutions, most of whom cannot legally give their consent to anything.

They are, in effect, a captive audience; totally dependent upon the Welfare Department for medical care. They cannot choose their physician, approve or disapprove of a treatment technique or agree or disagree to take part in a medical experiment.

OLD STORY

The controversy over regulating medical experiments with humans is not new. Nor is the aspect of controlling experimentation on humans in institutions. In 1948, the Nuremberg military tribunals set forth a 10-point code for clinical research with humans as a reaction to the horrors depicted in Nazi death camps.

The first point reads "The voluntary consent of the human subject is absolutely essential."

Despite the semantic strength of the "code," it was more than 15 years before the philosophy of getting a patient's consent was actually codified in the United States.

It was not until Congress passed a series of amendments to the Food, Drug and Cosmetic Act which strengthened control over the testing and marketing of new drugs. Specifically the legislation empowered the Food and Drug Administration to require drugs be tested for efficacy as well as safety and set down a framework of required "clinical" investigations.

HILL ACTION

New York Sen. Jacob Javits was successful in attaching a rider to this bill which required that the doctors employed by the drug companies or other testing agency explain the test to a patient and obtain consent.

The 1962 law, however, actually shut only a few doors. In the initial regulations written by FDA, the manner of consent, that is whether written or oral, was not specified.

Furthermore it permited doctors to waive getting consent when they believed it was "justifiable" not to inform a patient.

At the same time human experimentation regulations have been painfully evolving, medical research in this country had skyrocketed.

Freeman H. Quimby, a science research specialist at the Library of Congress, prepared a report for Sen. Javits last year that found the American drug and medical research industry was spending 20 times as much in medical experimentation than it had in the 1940's. He estimated the gross expenditure at $2 billion.

He also found: "a growing need for larger numbers of human subjects per clinical trial so that the efficacy, side effects, and precautions for the increasing volume of the new drugs and biologicals can be established with statistical rigor before approval for general use by practicing physicians."

Dr. Henry K. Beecher, a Harvard medical professor, and critic of the standard of medical ethics in research work claims physicians are doing research work under other pressures:

"Medical schools and university hospitals are increasing dominated by (medical) investigators. Every young man knows that he will never be promoted to a tenure post or to a professorship in major medical school, unless he has proved himself as an investigator. If the ready availability of money for conduct research is added to the fact, one can see how great the pressures are on an ambitious young man."

In 1964, the World Medical Association met in Helsinki, Finland and adopted a set of standards for research on humans. This was later called the "Declaration of Helsinki," and won quick support from major U.S. medical associations. It specifically noted that consent should be obtained from relatives or legal guardians if the patient was incapable of rendering it. It said written consent was preferable.

TROUBLES

But two years later, when FDA Commissioner James Goddard issued a policy guide calling for "written consent" forms, the medical associations weren't so ready to go along.

"It is impossible for the commissioner to codify realistically, in the form of a policy statement, the legal requirements for valid consent under the myriad