

Researchers cutting down the risks

University paperwork makes projects safer

By CAROLYN BEAVER
Of the Emerald

Any participant in a University research project can be assured there will be no risks involved, or that the benefits outweigh the risks, says Fred Wilhelm, of the Committee for the Protection of Human Subjects.

All grant applications come through the Graduate School's Office of Scientific and Scholarly Research. If the grant involves "human subjects," Wilhelm sends the researcher a form asking for the project's specifics.

The form asks for a description of the research, the number of subjects to be used, the kinds of groups to be involved, the potential benefits to the subjects and to humanity and a detailed description of the "known or foreseeable risks." It also requires a list of planned safeguards employed and an example of an informed consent form.

"The University has always taken a look at this issue," says Wilhelm, but before 1971, it was on an informal basis. The committee was formed in 1971, and in 1975 it became even more specific when the Department of Health, Education and Welfare issued new, stricter regulations that required everyone applying for federal money to establish a board or committee.

A cross-section of the community makes up the University's committee.

When a project form is returned, Wilhelm picks two committee members to initially review it.

The full committee meets monthly to discuss the grants. Wilhelm estimates they consider seven or eight projects monthly. "The major problem investigators have is in identifying the risks and preparing an appropriate informed consent form," Wilhelm says. The consent form allows the subject complete information about the project.

The form should outline the risks and benefits, if a treatment is involved, should lay out an alternative which signifies the treatment is not a "cure-all," and should note the participation is voluntary.

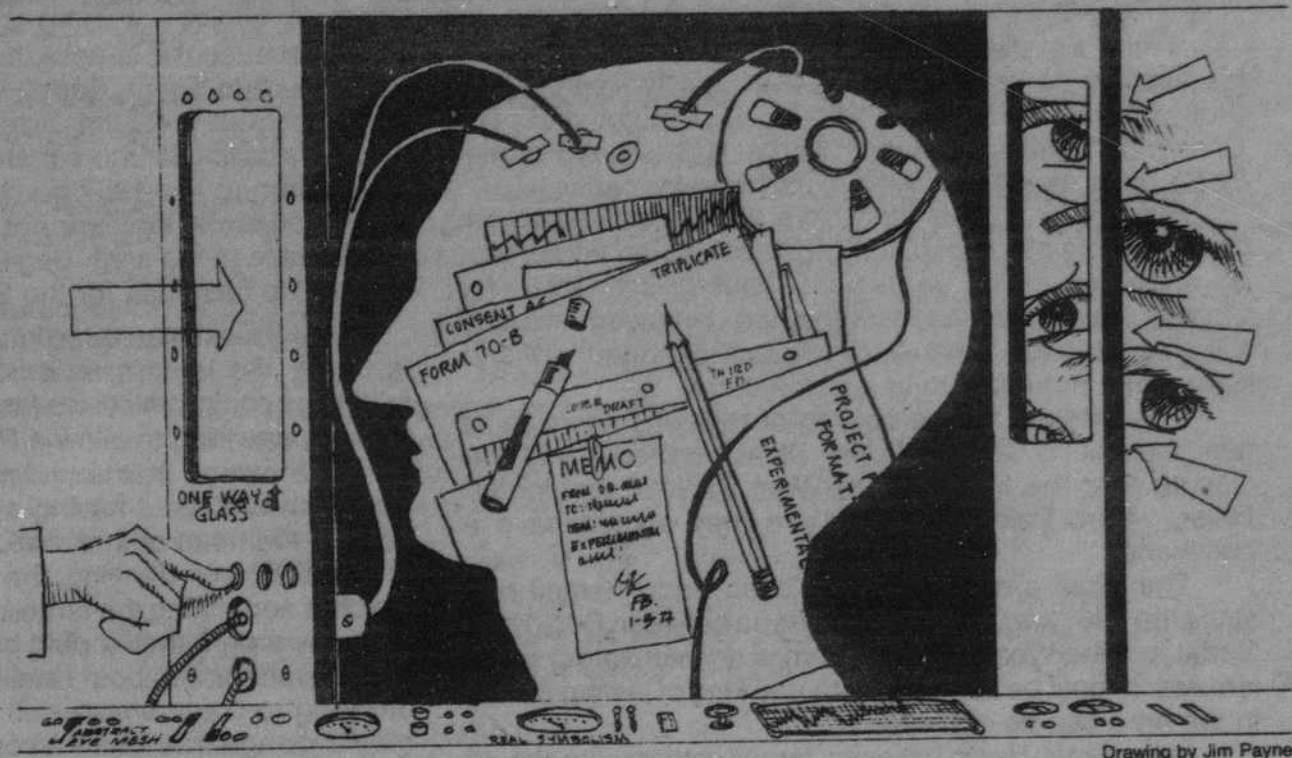
Parental or legal guardian consent is necessary when working with children or those who would not understand the consent form, says Wilhelm.

Problems may arise with the consent form, Wilhelm says. Many times "researchers feel if a subject is informed completely, it ruins the project."

If no risk is involved to the subject, sometimes the consent form can be modified.

Researchers must also identify risks involved for the subject, including invasion of privacy, and physical and psychological risks. When there are risks, safeguards must be provided them.

"A lot of the information investigators require is highly sensitive



and could cause embarrassment if it were to get out. Researchers are in a bind because knowledge must be pursued, but in a balanced way to protect those involved," says Wilhelm.

Wilhelm stresses not every risk has to have a corresponding safeguard, but the total risk/benefit ratio should be equal.

"If there was a great deal of risk, and not much benefit, the committee would probably say no," says Wilhelm. "If the benefits far exceeded the risks, that would be another story."

He says cases rest on "their own merits."

"Some researchers feel the committee is an infringement on their integrity," Wilhelm says. It

sets up a barrier because they have to go through a process."

"The forms have had a lot more positive benefits because of the awareness it has instilled in researchers," Wilhelms says. "They're more aware of things that would be considered a breach of ethics now."

A few years ago, if a professor

wanted to find out what effects stress had on students, he or she could have given the students a test back marked 'F,' just to see what the reaction would be. Because of the committee, the professor would now have to take many other factors into consideration before this could be done, says Wilhelm.

Prof receives biology grant

A University chemistry professor has received a \$750,000, five-year federal grant extension for the continuation of a study begun at the University 10 years ago.

Peter von Hippel, director of the University's Institute of Molecular Biology, is heading the research project.

The director was the "principle investigator" when the study was first started at the University 10 years ago. He says the study will continue to look at how protein molecules recognize specific sequences of DNA and "turn them on."

According to von Hippel, 10 post-doctoral research as-

sociates, graduate students and technicians are focusing on the control mechanisms in bacterial and viral systems.

"What we want to understand is how the biological mechanisms of this protein recognition process work," he says. "We want to know what actual molecular events are occurring in the process."

He points out that the U.S. Public Health Service and the National Institute of Health are financing

the research because it may have medical applications.

Von Hippel says, "If we can understand the process, we may be able to manipulate the process. This manipulation might be applicable to the treatment of cellular diseases such as cancer."

Pointing out the value of studying the recognition process, von Hippel says, "The best applied research is based on basic research."

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