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The Faculty Council Committee on Research met on Tuesday, September 22, to discuss clearance of research projects entailing the use of human subjects. Present were Drs. Gaffney, Gall, Knowles, Lichstein, and Pratt.

It was the recommendation of the Committee that prior approval should be sought in all investigations in which new drugs, biologic substances or radiobiologic methods are to be applied experimentally in human subjects. This ruling should prevail throughout the Medical Center.

It was felt that each investigator should be required to submit his experimental plan to the Director of his own department who could by any means he wished evaluate and approve the project. In the larger divisions this could be accomplished by a departmental committee designated for this purpose. At the discretion of the departmental director and/or the Dean's Office the investigator may be required to submit his plan to the Research Committee of Faculty Council, which would then review it and make its recommendations.

It was also recommended that no steps be taken by the Faculty to develop a standard form for (volunteer) patient consent in connection with human experimentation. This, in no way, however, should free the investigator of establishing rapport with the subject (or his family) and making known to him in advance the nature of the investigation and of procuring his consent.

A proposed statement of general principles pertaining to Medical Center policy in research projects utilizing human volunteers is attached. This is submitted to Faculty Council for approval and may thus serve as a broad guideline.

Harvey Knowles, M.D.
Thomas E. Gaffney, M.D.
Norman C. Lichstein, M.D.
Edward L. Pratt, M.D.
Edward A. Gall, M.D., Chairman

10/1964

Guidelines For Clinical Investigation With Human Subjects

It is fully appreciated that it may be difficult to draw a sharp line between investigation and progressive medical practice.

In general, clinical investigation shall be considered to exist if an agent or procedure which has not before been utilized for a specific therapeutic or diagnostic reason is to be applied in order to determine its significance, efficacy or method of use. The following principles will obtain whether a single person or a group of individuals are to be investigated.

The danger of the investigation must have been thoroughly probed prior to its initiation, by animal studies if possible.

The investigation must be of such order that the results when obtained will be valid and, if successful, will be of benefit to mankind.

The investigation must be properly designed and carried out under careful medical supervision.

The voluntary consent of the person (s) on whom the investigation is to be performed must be obtained. The volunteer should be aware insofar as possible of the nature of the study and its implications.