§ 2444. Human research review committees. 1. Each public or private institution or agency which conducts, or which proposes to conduct or authorize, human research, shall establish a human research review committee. Such committee shall be composed of not less than five persons, approved by the commissioner, who have such varied backgrounds as to assure the competent, complete and professional review of human research activities conducted or proposed to be conducted or authorized by the institution or agency. No member of a committee shall be involved in either the initial or continuing review of an activity in which he has a conflicting interest, except to provide information required by the committee. No committee shall consist entirely of persons who are officers, employees, or agents of, or who are otherwise associated with the institution or agency, apart from their membership on the committee, and no committee shall consist entirely of members of a single professional group.

2. The human research review committee in each institution or agency shall require that institution or agency to promulgate a statement of principle and policy in regard to the rights and welfare of human subjects in the conduct of human research, and the committee and the commissioner shall approve that statement prior to its taking effect. The committee shall review each proposed human research project to determine (1) its necessity; (2) that the rights and welfare of the human subjects involved are adequately protected, (3) that the risks to the human subjects are outweighed by the potential benefits to them or by the importance of the knowledge to be gained; (4) that the voluntary informed consent is to be obtained by methods that are adequate and appropriate, and (5) that the persons proposed to conduct the particular medical research are appropriately competent and qualified. The committee shall periodically examine each existing human research project with regard to the proper application of the approved principles and policies which the institution or agency has promulgated. The committee shall report any violation to the commissioner. In addition to the voluntary informed consent of the proposed human subject as required by section twenty-four hundred forty-two of this chapter, the consent of the committee and the commissioner shall be required with relation to the conduct of human research involving minors, incompetent persons,

mentally disabled persons and prisoners.

3. Each person engaged in the conduct of human research or proposing to conduct human research shall affiliate himself with an institution or agency having a human research review committee, and such human research as he conducts or proposes to conduct shall be subject to review by such committee in the manner set forth in this section.