

## PROCEDURES FOR SUBMISSION

FEDERAL DEFINITION OF RESEARCH - A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

EXEMPT – These are retrospective medical record studies or anonymous surveys for which there is no identifying information being kept and there will be no link to go back and get further information, and the disclosure of data could not reasonably place the subjects at risk of civil or criminal liability or be damaging to the subjects’ financial standing, employability or reputation; and the research involves the use of existing data, documents, or specimens.

Please complete the exempt form, including required signatures, and submit to the Office for Human Subjects Research.

EXPEDITED – These are research activities that 1) present no more than minimal risk (risk not greater than that ordinarily encountered in daily life) to human subjects, and 2) involve only procedures listed in one or more of the categories listed on the first page of the submission form.

Please complete the full committee/expedited form, including required signatures, and submit two copies of all information including consent when appropriate to the Office for Human Subjects Research.

FULL COMMITTEE – All others fall under this category including both biomedical and behavioral studies that present more than minimal risk or that do not fall into the exempt or expedited categories.

Please complete the full committee/expedited form, including required signatures, and submit two copies of the form, protocol, consent on standard consent paper, investigator brochure, if applicable, recruitment information, and any other applicable information to the Office of Human Subjects Research.