## **Research Involving Human Subjects**

The rights of all human subjects involved in NIH-supported research are of paramount importance to the Federal Government. Safe-guarding these rights is primarily the responsibility of the institution that receives or is accountable for the funds awarded for support of the research. However, NIH also relies on its SRGs and Advisory Councils to evaluate all applications and proposals involving human subjects for compliance with human subject regulations (Code of Federal Regulations, Title 45 Part 46).

The NIH will fund research covered by the regulations only if the institution has filed an assurance with the Office for Human Research Protections (OHRP) and has certified that the research has been approved by an institutional review board (IRB), a board at the requesting institution formed solely for this purpose.

SRGs assign the following codes to applications to indicate their judgment as to compliance with these concerns (codes appear on the summary statement):

The evaluation by Council will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the proposed research to the subjects and others, and the importance of the knowledge to be gained. The URL address is: http://ohrp.osophs.dhhs.gov/

No awards will be made until all expressed concerns about human subjects have been resolved to the satisfaction of the NIH.