

'RISKS' IN RESEARCH ON HUMANS

A risk is a potential harm (injury) associated with the research, that a reasonable person in the subject's position would likely consider significant in deciding whether or not to participate in the research.

- * The concept of risk includes discomfort, burden, or inconvenience that a research subject may experience as a result of the research procedures.
- * Underlying the consideration of risk is the ethical obligation of the investigator not to harm subjects of research and also to minimise potential risk to the greatest extent possible.

The five major types of risks are:

- * physical risk (eg. pain, bruising and infection associated with venipuncture, adverse reactions to drugs, muscle soreness and pain as a consequence of exercise testing, heart attack induced by maximal exercise test);
- * psychological risk (eg. depression and confusion as a result of administration of drugs, feelings of guilt precipitated by a sensitive survey);
- * social risk (eg. invasion of privacy, loss of community standing);
- * legal risk (eg. criminal prosecution or revocation of parole); and
- * economic risk (eg. loss of employment, loss of potential monetary gain).

CLASSIFICATION OF RISKS

- **Minimal risk** is present when the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. The expression "minimal risk" is the baseline or standard by which research risk is measured.

Examples of "minimal risk" procedures include electrocardiography, collection of blood by venipuncture from healthy adults who are not pregnant, moderate exercise testing, administration of standard psychological tests with only a minor level of associated stress, and magnetic resonance imaging.

- **Less than minimal risk** is present in the case of procedures such as collection of urine, collection of sweat, weighing, pulse measurement, blood pressure measurement, voice recordings, skin fold body composition measurements, and any standard psychological testing with no stress.
- **Greater than minimal risk** procedures include the administration of drugs, IV catheterisation, radiology exams (x-ray, CT scan), maximal exercise testing and stressful psychological testing.
- **Significant risk** procedures include chemotherapy, radiation therapy, and major surgery.