

Section 9: Degree of Risk

The risks to participants should be justified in relationship to the anticipated benefits. The IRB must determine that risks are managed to the extent possible consistent with sound research design.

The federal regulations define risk as the probability of harm or injury (physical, social, or economic) occurring as the result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant.

(Source: OHRP IRB Guidebook)

9.1 Minimal Risk

Minimal risk protocols are those for which the anticipated risks for these trials are no greater than those ordinarily met in daily life or during the performance of routine physical or psychological examinations (e.g., blood draw, urine sample).

DFCI IRB policy does not allow investigators to obtain samples (e.g., blood) for minimal risk trials from employees who are under their direct supervision.

Examples of minimal-risk protocols include but are not limited to:

- Data collection from medical record reviews, laboratory test results, and pathology records
- Questionnaires or surveys of participants that meet the no-greater-than-minimal-risk definition
- Laboratory investigation using human subject samples such as limited amounts of blood drawn from research participants
- Collection of discarded tissues or other samples

Minimal risk protocols may or may not require review by a full IRB.

9.2 Greater than Minimal Risk

Greater than minimal risk protocols place participants at higher risk than those ordinarily met in daily life or during the performance of routine physical care and include such examples as chemotherapy, or taking of bone marrow. These protocols usually involve investigational drugs, new treatment methods or invasive procedures, or are clinical trials that will yield generalizable knowledge about the disease or subject population.