# Required Elements of a Protocol

Basic IRB Findings Federal regulations require the IRB review certain elements when making determination on studies involving human subjects even the study is minimal risk. The IRB must find the elements in each protocol considered by the IRB as an approvable protocol. The protocol must include detailed justification on the following eight elements:

1. Risks to subjects are minimized by using sound research design and not expose subjects to unnecessary risks.
2. Risk are reasonable in relation to anticipated benefit -therefore the protocol must include a list of risk and benefits.
3. Selection of subjects is equitable. The protocol should cover: -Number of subjects. -Gender of Subjects. -Age of Subjects. -Racial and Ethnic Origin. -Inclusion Criteria/exclusion Criteria. -Vulnerable Subjects.
4. How informed consent will be sought form each participant -Method of Subject Identification and Recruitment. -Process of Consent. -Costs to the Subject. -Payment for Participation.
5. Documentation of Consent
6. Monitoring of data to ensure safety -when appropriate
7. Provisions to protect privacy and confidentiality of subjects
8. If any subjects will be vulnerable to coercion -how the subjects will be protected.

For details regarding how to draft a protocol see the IRB's Basic Guidelines for Research Protocols.