

Research Consent Document

Information that must be provided to potential subjects

1. Research purpose and procedures
 - a. A statement that the study involves research
 - b. An explanation of the purposes of the research
 - c. The expected duration of the subject's participation
 - d. A description of the procedures to be followed
 - e. Identification of any procedures that are experimental
2. Risks and discomforts
3. Potential benefits
4. Alternative procedures or treatments
5. Provisions for confidentiality
6. Management of research-related injury (if risk is greater than minimal)
7. Contacts for additional information
8. Voluntary participation and the right to discontinue participation without penalty

Information that must be provided when applicable

9. Unforeseeable risks
10. Termination of participation by the investigator
11. Additional costs
12. Consequences of discontinuing research participation
13. Notification of significant new findings
14. Approximate number of subjects