



ST. JOHN HOSPITAL & MEDICAL CENTER

DEVICES: ASSESSMENT OF RISK CHECKLIST

_____ **Significant Risk Device:** Significant risk device is an investigational device that:

_____ Is intended for implant and presents a potential for serious risk to the health, safety, or welfare of a subject

_____ Is for use in supporting or sustaining human life and represents a potential for serious risk to the health, safety, or welfare of a subject

_____ Is for use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject

_____ Otherwise presents a potential for serious risk to a subject

_____ **Non-Significant Risk Device:** Non-significant risk devices are devices that do not pose a significant risk to the human subjects. Examples include most daily-wear contact lenses, ultrasonic dental scalers, and foley catheters.

_____ **Intermediate (Moderate) Risk:** Activities involving a wide range of medical, social, and behavioral projects, in which there is no immediate physical risk to the subject, are considered to be in an "intermediate risk" category. Examples include personality inventories; interviews; questionnaires; the dissemination of any data or information concerning an identified individual; information gathering activities conducted in classrooms or elsewhere; individual or group therapy sessions; or the use of photographs, taped records, and stored data. Since some of these of procedures may impose a varying degree of demeaning or dehumanizing conditions, prior written informed consent is required. However, since this type of activity does not involve physical invasion but is where voluntary consent on the part of the subject is desirable, a more simplified consent is acceptable.

_____ **Low Risk:** Certain activities are classified as "low risk" and may not require a written informed consent. An example is the use of completely anonymous questionnaires. If a written informed consent is deemed unnecessary or undesirable in a particular instance a waiver of written consent may be requested. Low risk involves situations in which there is no conceivable physical or mental discomfort, and the measurements made on subjects can be considered to be reasonably unobtrusive. In these situations written informed consent may be waived.