Human Subjects
Office of Research
UNIVERSITY OF GEORGIA

IRB Review and Medical Devices

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Types of Device Studies

1. Exempt

2. Non Significant Risk

3. Significant Risk

What is a Significant Risk Study?

1. Intended as an implant and presents a potential for serious risk to the health, safety, or welfare of the subject

2. Is represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject.

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

4. Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

The sponsor (investigator) is responsible for making the initial risk determination and presenting it to the IRB.

Unless the FDA has already made a risk determination for the study, the IRB must review the sponsor (investigator) significant risk or non-significant risk determination.

If the FDA has already made the significant risk or non-significant risk determination, it is final.

Making the Significant vs. Non-Significant Risk Determination

The IRB must make two separate decisions, based on different criteria

1. Is the investigation approvable or not? The criteria for deciding if a study is a SR or NSR device can be approved are the same as those used to evaluate any proposed research project.

2. Does the device present SR or NSR?

IRBs should make the significant risk or non significant risk determination by reviewing relevant information at a convened meeting.

This should include: description of the device, reports of prior investigations conducted with the device, the proposed investigational plan, and subject selection criteria.

An IRB may agree or disagree with the sponsor's initial assessment.

The IRB should document its significant risk or non significant risk determination in the meeting minutes. The minutes should describe its reasoning for said determination.

What is the basis for the risk determination?

The determination of significant risk depends on the use of the device in the particular study, as well as the inherent risks of the device itself. But not the device alone

What is the nature of harm that may result from the use of the device?

Significant risk studies are those that present a potential for serious risk to the health, safety, or welfare of a subject. Included among those devices that present significant risk are devices which the potential for harm could be life-threatening, could result in permanent impairment of a body function, or permanent damage to body structure, or could necessitate medical or surgical intervention to preclude permanent impairment of a body function or body structure.

Will the subject need to undergo an additional procedure as part of the study?

IRBs should consider the potential harm the procedure could cause as well as the potential harm caused by the device.

The Determination

The IRB may agree or disagree with the investigator's initial risk assessment. If the IRB agrees, the investigation may proceed without FDA approval after the IRB approves the study.

This is considered an abbreviated IDE

If the IRB disagrees with the non significant risk determination, the investigator must seek an IDE from the FDA and then return to the IRB before the investigation may take place.

Examples

A pacemaker that is a modification of a commercially available pacemaker poses significant risk because the use of any pacemaker presents a potential for serious harm.

An extended wear contact lens is considered significant risk because the risk of wearing the lens continuously for 30 days presents a potential for injuries not normally seen with daily wear lenses which are non-significant risk.