GUID D86-1: GUIDANCE ON SIGNIFICANT AND NONSIGNIFICANT RISK DEVICE STUDIES

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The attached guidance on how to identify a significant and nonsignificant risk device study was developed principally for institutional review boards (IRBs) and sponsors of investigations. It was developed from input from ODE Division Directors and other staff. Even though it is aimed at IRBs and sponsors, all ODE reviewers should be familiar with its contents.

Attachment

GUIDANCE ON SIGNIFICANT AND NONSIGNIFICANT
RISK DEVICE STUDIES

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An approved Investigational Device Exemption (IDE), or an exemption from the IDE regulation, permits clinical study of unapproved devices. The IDE regulation describes two types of device studies--significant risk (SR) and nonsignificant risk (NSR).

The IDE regulation defines a SR device study as one that presents a potential for serious risk to the health, safety, or welfare of a subject; and, is an implant, is used in supporting or sustaining human life, is of substantial importance in diagnosing, curing, mitigating or treating disease, otherwise prevents impairment of human health, or otherwise presents a potential for serious risk to the health, safety, or welfare of a subject. A NSR investigation is one that does not pose a SR.