Acceptance of Foreign Clinical Studies - Information Sheet

Guidance for Institutional Review Boards and Clinical Investigators

The Food and Drug Administration (FDA) may accept clinical studies conducted outside the United States in support of safety and efficacy claims for drugs, biological products and medical devices.

All drug, biologic and device studies conducted under an Investigational New Drug (IND) or Investigational Device Exemption (IDE) are governed by the FDA informed consent and IRB requirements. [See 21 CFR part 312 IND regulations and 21 CFR part 812 IDE regulations.]

Under 21 CFR 312.120(c)(1), FDA will accept a foreign clinical study involving a drug or biological product not conducted under an IND. On April 28, 2008, FDA issued a final rule modifying 21 CFR 312.120, entitled Human Subject Protection; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application. This final rule and its preamble are available at **http://www.regulations.gov/#!documentDetail;D=FDA-2004-N-0061-0002;oldLink=false (http://www.regulations.gov/#!documentDetail;D=FDA-2004-N-0061-0002;oldLink=false)**.

Under 21 CFR 814.15(a) and (b), FDA will accept a foreign clinical study involving a medical device not conducted under an IDE only if the study conforms to whichever of the following provides greater protection of the human subjects:

- the ethical principles contained in the 1983 version of the Declaration of Helsinki, or
- the laws and regulations of the country in which the research was conducted.

Also see these FDA Information Sheets:
Non-Local IRB Review (/RegulatoryInformation/Guidances/ucm126423.htm)
Waiver of IRB Requirements for Drug and Biologic Studies (/downloads/RegulatoryInformation/Guidances/UCM126500.pdf)
Guide to Informed Consent (/RegulatoryInformation/Guidances/ucm126431.htm)

More in Search for FDA Guidance Documents (/RegulatoryInformation/Guidances/default.htm)

FDA Guidance Documents: General and Cross-Cutting Topics

(/RegulatoryInformation/Guidances/ucm122044.htm)

Advisory Committee Guidance Documents (/RegulatoryInformation/Guidances/ucm122045.htm)

Clinical Trials Guidance Documents (/RegulatoryInformation/Guidances/ucm122046.htm)

Combination Products Guidance Documents (/RegulatoryInformation/Guidances/ucm122047.htm)

Import and Export Guidance Documents (/RegulatoryInformation/Guidances/ucm122048.htm)

International Council for Harmonisation (ICH) Guidance Documents (/RegulatoryInformation/Guidances/ucm122049.htm)

Veterinary International Conference on Harmonization (VICH) Guidance Documents (/RegulatoryInformation/Guidances/ucm122050.htm)