(39) US Department of Health, Education, and Welfare (1977)
General Considerations for the Clinical Evaluation of Drugs
(HEW Pub No: (FDA) 77-3040)
Public Health Service, Food and Drug Administration, Rockville, Md.

Preamble
These guidelines are very brief and can be accessed online (https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM071682.pdf) together with many others issued by FDA, for example, *General considerations for the clinical evaluation of drugs in infants and children (1977).*

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM071682.pdf

Aims
The purpose of these guidelines is to present acceptable current approaches to the study of investigational drugs in man. These guidelines contain both generalities and specifics and were developed from experience with available drugs. It is anticipated that with the passage of time these guidelines will require revision. These guidelines are not to be interpreted as mandatory requirements by the FDA to allow continuation of clinical trials with investigational drugs or to obtain approval of a new drug for marketing. These guidelines, in part, contain recommendations for clinical studies which are recognised as desirable approaches to be used in arriving at conclusions concerning safety and effectiveness of new drugs (Foreword, page iii).

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- *B. Principles of informed consent*

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Definitions
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- *B. Qualifications of investigators*
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Women of childbearing potential
Male reproductive system
Evaluation in children

Authors
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