

42 C.F.R. § 11.62

What requirements apply to applicable clinical trials for which submission of clinical trial information has been determined by the Director to be necessary to protect the public health?

- (a) A responsible party who receives notification that the Director has determined that posting of clinical trial information for an applicable clinical trial described in paragraph (b) of this section is necessary to protect the public health must submit clinical trial information as specified in paragraph (c) of this section.
- (b) An applicable clinical trial subject to this section must be either:
- (1) An applicable clinical trial of an approved, licensed, or cleared drug product (including a biological product) or device product that has a primary completion date on or after September 27, 1997; or

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