
40 C.F.R. § 26.1603

EPA review of proposed human research.

- (a) EPA must review all proposals for new human research submitted under § 26.1125 in a timely manner.
- (b) In reviewing proposals for new human research submitted under § 26.1125, the EPA Administrator must consider and make determinations regarding the scientific validity and reliability of the proposed research, including:
- (1) Whether the research would be likely to produce data that address an important scientific or policy question that cannot be resolved on the basis of animal data or human observational research.
 - (2) Whether the proposed research is designed in accordance with current scientific standards and practices to:
 - (i) Address the research question.
 - (ii) Include representative study populations for the endpoint in question.
 - (iii) Have adequate statistical power to detect appropriate effects.
 - (3) Whether the investigator proposes to conduct the research in accordance with recognized good research practices, including, when appropriate, good clinical practice guidelines and monitoring for the safety of subjects.
- (c) In reviewing proposals for new research submitted under § 26.1125, the EPA Administrator must consider and make determinations regarding ethical aspects of the proposed research, including:

This document is only available to subscribers. Please [log in](#) or [purchase access](#).

[Purchase Login](#)