


## CFR - Code of Federal Regulations Title 21

[FDA Home](#) [Medical Devices](#) [Databases](#)



 **The information on this page is current as of Dec 22, 2023.**

For the most up-to-date version of CFR Title 21, go to the [Electronic Code of Federal Regulations \(eCFR\)](#).

New Search

[Help](#) | [More About 21CFR](#)

TITLE 21--FOOD AND DRUGS  
CHAPTER I--FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
SUBCHAPTER A - GENERAL  
PART 50 [PROTECTION OF HUMAN SUBJECTS](#)

### Subpart A - General Provisions

- [§ 50.1](#) - Scope.
- [§ 50.3](#) - Definitions.

### Subpart B - Informed Consent of Human Subjects

- [§ 50.20](#) - General requirements for informed consent.
- [§ 50.22](#) -
- [§ 50.23](#) - Exception from general requirements.
- [§ 50.24](#) - Exception from informed consent requirements for emergency research.
- [§ 50.25](#) - Elements of informed consent.
- [§ 50.27](#) - Documentation of informed consent.

### Subpart C [Reserved]

### Subpart D - Additional Safeguards for Children in Clinical Investigations

- [§ 50.50](#) - IRB duties.
- [§ 50.51](#) - Clinical investigations not involving greater than minimal risk.
- [§ 50.52](#) - Clinical investigations involving greater than minimal risk but presenting the prospect of direct benefit to individual subjects.
- [§ 50.53](#) - Clinical investigations involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects' disorder or condition.
- [§ 50.54](#) - Clinical investigations not otherwise approvable that present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.
- [§ 50.55](#) - Requirements for permission by parents or guardians and for assent by children.
- [§ 50.56](#) - Wards.

Authority: 21 U.S.C 321, 343, 346, 346a, 348, 350a, 350b, 352, 353, 355, 360, 360c-360f, 360h-360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b-263n.

Source: 45 FR 36390, May 30, 1980, unless otherwise noted.