Federal Criteria for IRB Levels of Review

Administrative reference • Revised Common Rule (2018 Requirements) • November 2026

Purpose: A practical summary of federal review pathways under 45 CFR part 46. This guide is not an institutional policy or a substitute for checking applicable subparts, funding terms, FDA rules, and SU procedures.

At-a-glance comparison

Pathway	Federal threshold	Who reviews / consequence
Not human subjects research	Not research and/or does not involve human subjects as defined in §46.102	Outside Common Rule IRB review; document institutional determination
Exempt	Human subjects research fits an applicable §46.104(d) exemption, subject to restrictions	Institutional determination; limited IRB review for specified exemptions
Expedited	No more than minimal risk AND eligible listed category, or qualifying minor change (§46.110)	IRB chair or designated experienced IRB member(s)
Convened (full committee)	Nonexempt research not eligible for expedited review; often greater than minimal risk	Quorum and majority approval at convened IRB meeting

1. First determine whether the activity is human subjects research

Research (§46.102(l)): a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Certain scholarly/journalistic activities, public health surveillance, criminal justice activities, and authorized intelligence/operational activities are expressly excluded as defined in the regulation.

Human subject (§46.102(e)): a living individual about whom an investigator obtains information or biospecimens through intervention or interaction and uses, studies, or analyzes them; OR obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. Publication intent alone does not determine whether an activity is research.

2. Exempt research — §46.104(d)

1. Educational practices — Research in established or commonly accepted educational settings involving normal educational practices, with specified protections against adverse effects on learning or educator assessment.

2. Educational tests, surveys, interviews, observation — Eligible interactions when information is nonidentifiable, disclosure would not reasonably place subjects at specified risk, or limited IRB review confirms privacy/confidentiality protections. Special restrictions apply to children.

3. Benign behavioral interventions — Adults prospectively agree to brief, harmless, painless, noninvasive interventions; additional recording/disclosure and deception conditions apply.

4. Secondary research uses — Certain uses of identifiable private information or biospecimens, including publicly available information, nonidentifiable recording, HIPAA-regulated uses, or qualifying federal information activities.

5. Federal public benefit/service programs — Research or demonstration projects conducted or supported by federal departments/agencies meeting specified conditions.

6. Taste and food quality — Consumer acceptance and taste/food quality evaluation studies meeting food-safety conditions.

7. Storage or maintenance — Storage/maintenance of identifiable private information or biospecimens for secondary research with broad consent and limited IRB review.

8. Secondary research with broad consent — Secondary use of identifiable private information or biospecimens meeting broad-consent, documentation, and limited-review requirements.

Important: Exempt does not mean "no protections." Applicability of subparts B, C, and D and agency-specific restrictions must be checked. Categories 7 and 8 require broad-consent infrastructure; do not assume SU implements them. Limited IRB review is required for the specific pathways in §46.104(d)(2)(iii), (3)(i)(C), (7), and (8).

3. Expedited review — §46.110

Two conditions generally must both be met: (a) no more than minimal risk as defined in §46.102(j); and (b) procedures fit one or more federally published expedited categories. A qualifying minor change to previously approved research during the approval period can also be reviewed through expedited procedures. "Expedited" describes the review process, not guaranteed turnaround time.

Published expedited categories (1998 OHRP list): 1 drug/device studies meeting special conditions; 2 blood collection within limits; 3 prospective collection of biological specimens by noninvasive means; 4 noninvasive clinical procedures routinely employed in clinical practice; 5 research using materials collected or to be collected solely for nonresearch purposes; 6 voice/video/digital/image recordings for research; 7 research on individual/group characteristics or behavior and certain surveys, interviews, focus groups, and program evaluations; 8 specified continuing review; 9 other continuing review when not under an IND/IDE and no additional risks identified.

An expedited reviewer may approve or require modifications but may not disapprove a protocol; disapproval requires convened IRB review. Privacy and confidentiality risks must be considered, including risk from disclosure of sensitive information.

4. Convened IRB (full committee) — §§46.108, 46.109, 46.111

Required for covered nonexempt research that cannot appropriately use expedited review, including research exceeding minimal risk. Review at a convened meeting requires a majority of members present, including at least one member whose primary concerns are nonscientific; approval requires a majority of those present. IRB approval criteria include minimized risks, reasonable risk/benefit relationship, equitable selection, consent, privacy/confidentiality, safety monitoring where appropriate, and safeguards for vulnerable participants.

5. Continuing review and modifications

Under §46.109(f), continuing review generally is not required for expedited-eligible research, research subject to specified limited IRB review, or research that has progressed to only approved data analysis or access to follow-up clinical data from clinical care, unless the IRB determines otherwise. Convened-review research otherwise receives continuing review at least annually under §46.109(e). For research subject to pre-2018 rules or FDA requirements, different obligations may apply.

A renewal/continuing review is not automatically an amendment. Changes to recruitment, procedures, data collection, populations, consent, or other approved study elements should be assessed and submitted through

the applicable modification process before implementation, except when necessary to eliminate immediate hazards.

Primary federal sources

- 45 CFR 46.102 (definitions): https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/section-46.102
- 45 CFR 46.104 (exemptions): https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/section-46.104
- 45 CFR 46.108–46.111 (IRB review and approval): https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46
- OHRP expedited categories: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html