IRB Registration and Federalwide Assurance (FWA) Alignment

Last reviewed October 2026 · https://www.integralhs.com/ohrp-irb-registration-fwa

What to have ready

Each item ties to the OHRP pages and FWA terms (read October 2026) or 21 CFR 56.106, as cited.

- A determination of whether the institution is "engaged in nonexempt human subjects research conducted or supported by" HHS or another agency that uses OHRP's FWA (OHRP [https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/index.html]).
- A list of the federal departments and agencies supporting your research, since the FWA terms reach research supported by "any U.S. federal department or agency that has adopted the Common Rule" (Terms of the FWA [https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html]).
- The registration record for each IRB that reviews HHS-conducted or supported research (OHRP, IRB Registration [https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-registration/index.html]).
- An IRB registration calendar: "Update an IRB registration within 90 days after a change in contact person or chairperson, and renew IRB registration every 3 years" (OHRP, IRB Registration). For IRBs reviewing FDA-regulated investigations, 21 CFR 56.106(e) also requires reporting within 30 days a decision to review new types of FDA-regulated products or to stop reviewing FDA-regulated investigations, and within 30 days of permanently ceasing review if the IRB disbands (21 CFR 56.106(e) [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56/subpart-B/section-56.106]).
- An FWA calendar. "The FWA is effective for 5 years and must be renewed every 5 years, even if no changes have occurred" (OHRP, Update or Renew an FWA [https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/update-renew-fwa/index.html]).
- Named holders of the roles the FWA tracks, with a 90-day update control: the institution "must update its FWA within 90 days after changes occur regarding the legal name of the institution, the Human Protections Administrator, or the Signatory Official" (OHRP, Update or Renew an FWA).
- Written reliance documentation. "The institution and the organization operating the IRB must document the reliance and the responsibilities that each entity will undertake to ensure compliance with the requirements of the Common Rule" (Terms of the FWA [https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html]).
- For IRBs reviewing FDA-regulated investigations, FDA registration records and a renewal date: "Each IRB must renew its registration every 3 years" (21 CFR 56.106(c) [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56/subpart-B/section-56.106]).