PART 1: IRBs v. FWAs at a glance

All U.S. federally funded non-exempt[1] research involving human subjects:
(1) must be approved by an IRB
AND
(2) must be conducted under a Federalwide Assurance (FWA).

BOTH of these criteria apply! Not "either/or". IRBs and FWAs are NOT interchangeable. **IRBs are a *component* of an institution's assurance of compliance (FWA). They are *not a substitute* for an assurance of compliance.**

	IRBs/ Ethics Committees/Research Ethics Boards	FWA
Description	An **institutional review board (IRB)** is an oversight committee that follows specific U.S. requirements for approval of human research projects under the "Common Rule."[2] Institutions/organizations use a variety of other names for their oversight committees such as "Ethics Committee", "Research Ethics Board", etc. For the purpose of this guidance, the term "IRB" will represent "oversight committees". The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy. IRBs or other authorized reviewers may also determine whether a project is "exempt from IRB review" (there are specific criteria for this determination), or whether a project is "research not involving human subjects" (RNIHS).	Each institution engaged[3] in research covered by The Common Rule is required to provide written assurance that it will comply with The Common Rule. **This written, legally binding assurance is called the Federalwide Assurance (FWA)**. The Federalwide Assurance is the only type of assurance of compliance accepted and approved by OHRP. An FWA is an **Institution's assurance** that research will be guided by a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution. FWAs are signed by the responsible Institutional Official. (*See OHRP[4]'s webpage for information on acceptable statements of principles*). The FWA must designate one or more IRBs that have registered with OHRP as the institution's IRB(s) of record. The FWA must be obtained prior to conducting any research involving human subjects. The FWA requirement also applies to research conducted in countries outside the U.S. when the research is federally funded by the U.S.

[1] Research that has received a determination of 'exempt from IRB oversight' or a determination of 'research not involving human subjects' (RNIHS) is not required to be covered under an FWA.
[2] "Common Rule": The Common Rule is a short name for "The Federal Policy for the Protection of Human Subjects" and has been adopted by a number of federal agencies since 1991. Each agency incorporated the policy into its own code of Federal Regulations (CFR), with DOD adapting it in Title 32 CFR Part 219, and the Department of Health and Human Services (DHHS) in Title 45 CFR Part 46.
[3] See OHRP's guidance on Engagement at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html.
[4] OHRP: Office of Human Research Protections, an Office within DHHS

	IRBs/ Ethics Committees/Research Ethics Boards	FWA
Applicability	All federally conducted or supported human research must be approved by an IRB or must have received a determination of "exempt" or RNIHS from an IRB or the institution's regulatory office, or otherwise be excluded from IRB consideration by an agency's policy. An institution or organization may have its own IRB, may rely on another IRB for all of its human research or for individual protocols, or may be required by the 2018 Common Rule to rely on a single IRB (sIRB) for collaborative (multi-site) research. When an institution or organization designates an external IRB for some or all of its research, they must enter into a written agreement between the relying institution/organization and the designated institution/organization. See "Agreements for external IRB oversight" below.	An FWA is required whenever an Institution or organization becomes **engaged** in human subjects research **conducted or supported[5]* by any U.S. federal department or agency that has adopted the Common Rule**, unless the research is otherwise exempt from the requirements of the Common Rule. An FWA is required whether the federally conducted or supported research is conducted at a U.S. institution or at a non-U.S institution. **This also applies to partnering or collaborating institutions/organizations conduct certain aspects of the research activities;** for example: local groups that recruit participants or conduct surveys, local hospital staffs that collect blood for research purposes, an NGO that administers investigational products, a company that tests devices for the purposes of FDA approval, etc.
IRB registration	All IRBs designated on an institution's/organization's FWA must be registered with OHRP before the FWA can be approved. See "How to apply" below. **IRB Registration is NOT the FWA.** IRB registration is a separate required component of the FWA[6].	All IRBs designated on an institution's/organization's FWA must be registered with OHRP before the FWA can be approved. See "How to apply" below. **IRB Registration is NOT the FWA.** IRB registration is a separate required component of the FWA.

[5] "Supported": U.S. Government provides any funding or other support including equipment, personnel, supplies, locations, etc.
[6] U.S. IRBs that review FDA-regulated studies must also register at the OHRP registration site: http://ohrp.cit.nih.gov/efile.

PRACTICALITIES		
	IRBs/ Ethics Committees/Research Ethics Boards	**FWA**
Information	https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/guidance-for-institutions-and-irbs/index.html for IRB registration	https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html for FWA application
How to apply	Registration at OHRP https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-registration/new-irb-registration/index.html	Approval by OHRP https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/file-a-new-fwa/index.html
Renewal / Updates	- Every 3 years, or - To register any additional IRB before it is designated under an FWA and reviews research conducted or supported by HHS - Within 90 days after changes regarding the contact person who provided the IRB registration information or the IRB chairperson - Within 90 days of a change in the membership roster if that IRB is designated under an FWA - Within 30 days after permanent cessation of an IRB's review of HHS-conducted or –supported research - Changes in FDA-regulated reviews to be done by the IRB	- Every 5 years, or Within 90 days after changes occur regarding the legal name of the Institution, the Human Protections Administrator, or the Signatory Official
Checking status	Search on the “IRB” tab of the OHRP website https://ohrp.cit.nih.gov/search/search.aspx?styp=bsc	Search on the “FWA” tab of the OHRP website https://ohrp.cit.nih.gov/search/search.aspx?styp=bsc