

Study Types with Descriptions and Examples

Study Type	Description	Examples	Review	
Non-Regulated	Not a systematic investigation designed to contribute to generalizable knowledge	-Quality assurance -Program evaluation -Health surveillance	-Case studies -Institutional process improvement	None*
Not Human Subjects	Use of samples or data with none of the 18 HIPAA identifiers, including zip codes or dates <u>of any kind</u>	-Use of commercially/publicly available samples/data -Use of repository samples or data with <u>no link</u> to original source patient		None*
Exempt	Meets the regulatory definition of <i>research involving human subjects</i> , and falls within one of the 8 Exempt categories defined at 45 CFR 46.104	-Chart reviews -Observational studies -Research on existing specimens (with or without HIPAA identifiers)	-Surveys -Comparing educational methods -Benign behavioral interventions	IRB Ofc
Minimal Risk** Non-Experimental	Observational – investigators may measure outcomes using diagnostic procedures, but treatments for routine care – participants <u>not</u> assigned to treatments for research purposes	-Chart reviews (some may be Exempt) -Noninvasive procedures (ex: behav health instruments) -Noninvasive collection of samples (ex: blood draws) -In-vitro diagnostic testing -Repositories		IRB Ofc
Minimal Risk** Experimental	Experimental – participants are assigned to one or more treatments (or control) for purposes of research, to measure intervention outcomes	-Minimal risk experimental interventions and non-invasive procedures (ex: blood draws, questionnaires) - <u>Not</u> incl. radiation or anesthesia (full board review)		IRB Ofc
Greater than Min. Risk	Procedures incur more risk to participant than that defined by Minimal Risk	-Invasive proc for research purposes, not clin care	-Clinical trials	Full IRB
External IRB	Relying on an External IRB (commercial or academic) to provide single IRB review and oversight, usually for multisite studies	-Multi-site NIH-funded study w/other inst as sIRB of record -Study for which Sponsor requires use of Advarra or WCG IRB for a Phase III drug trial		IRB Ofc & Ext IRB
Emergency Use	Life-threatening, severely debilitating, or serious condition req immediate treatment	- Unapproved drug/device used in emergency w/no time for IRB approval; IRB approval may be obtained <i>after</i> use		Contact IRB Ofc

***Non-Regulated / Not Human Subj:** IRB ofc rev required only for official IRB letter to publish/present; otherwise, use [NRHR tool](#).

****Minimal Risk:** probability and magnitude of harm or discomfort anticipated in research are not greater, in and of themselves, than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests.