Definition	ns: Old vs New
Common Rule (Old)	Final Rule (New)
Certification means the official notification by the institution to <b>the</b> pporting Federal department or agency component, in accordanc <b>the</b> it <b>b</b> quirements of this policy, that a research project or activity involv <b>ing</b> man subjects has been reviewed and approved by an IRB in accordance <b>avitb</b> approved <b>se</b> urance. 46.102(j)	
N/A	Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health related outcom <b>46</b> .102 (b)
Department or agency headeans the head any federal department or agence and any other officer or employee of any department or agency to whom aut has been delegated. 46.102(a) N/A	
Intervention includes both physical procedures by which data are gathered (f	<ul> <li>(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens 6.102 (e)(1)</li> <li>Intervention includes both physical procedures by which informatiobiospecimenare</li> </ul>
example,venipuncture and manipulations of the subject or the subject's environment that are performed for research purperset 202(f)	gathered (e.g., venipuncture) and manipulations of the subject or the subject's environm that are performed for research purposes.

IRB means an institutional review board established in accord with and for the purposes expressed in this policy. 102(g) IRB means an institutional review board established in accord with and for the purpose

IRB approvalmeans the determination of the IRB that the research has been IRB approvalmeans the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constrain this policy. the IRB and by other institutional and federal requirements 02(h)

	<ul> <li>(3) Collection and analysis of information, biospecimens, or records by or for a crimin justice agency for divities authorized by law or court order solely for criminal justice or criminal investigative purposes.</li> <li>(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national semisistics 46.102 (I)</li> </ul>
N/A	Written, or in writing, for purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic form <b>46</b> .102 (m)

Research Subject to Regulatioand similar terms are ioni2 (m)19.3 ni iten