

What is “design, conduct, or reporting of research?”

Research design is the creation of the plan, the strategy, the methodology, the procedures, and the structure of conducting a research study. Anyone involved in creating, developing, or substantively contributing to those aspects of scientific research is subject to the regulations. Similarly, persons who materially influence the research questions pursued are subject to the regulations.

Conduct of research pertains to the direction, execution, or management of the study plan. It includes all aspects of carrying out a study, including subject recruitment, selection, enrollment, or retention; data or specimen collection, analysis or interpretation; maintenance of regulatory binders and other study documents; data and safety monitoring, study drug or device accountability, and management of study-related records.

Reporting of research includes the reporting and attribution of adverse events; the presenting of data/results; submitting information to the IRB (*e.g.*, continuing review); completion of case report forms; and contributing to the presentation or publication of the research.

It is impossible to detail every component of what constitutes design, conduct, or reporting of research. Some interpretation by PIs will be needed. CHA expects all personnel to make a good faith effort to meet the spirit of the COI training and disclosure requirements and to seek guidance from the Office of the Chief Compliance Officer, as needed.