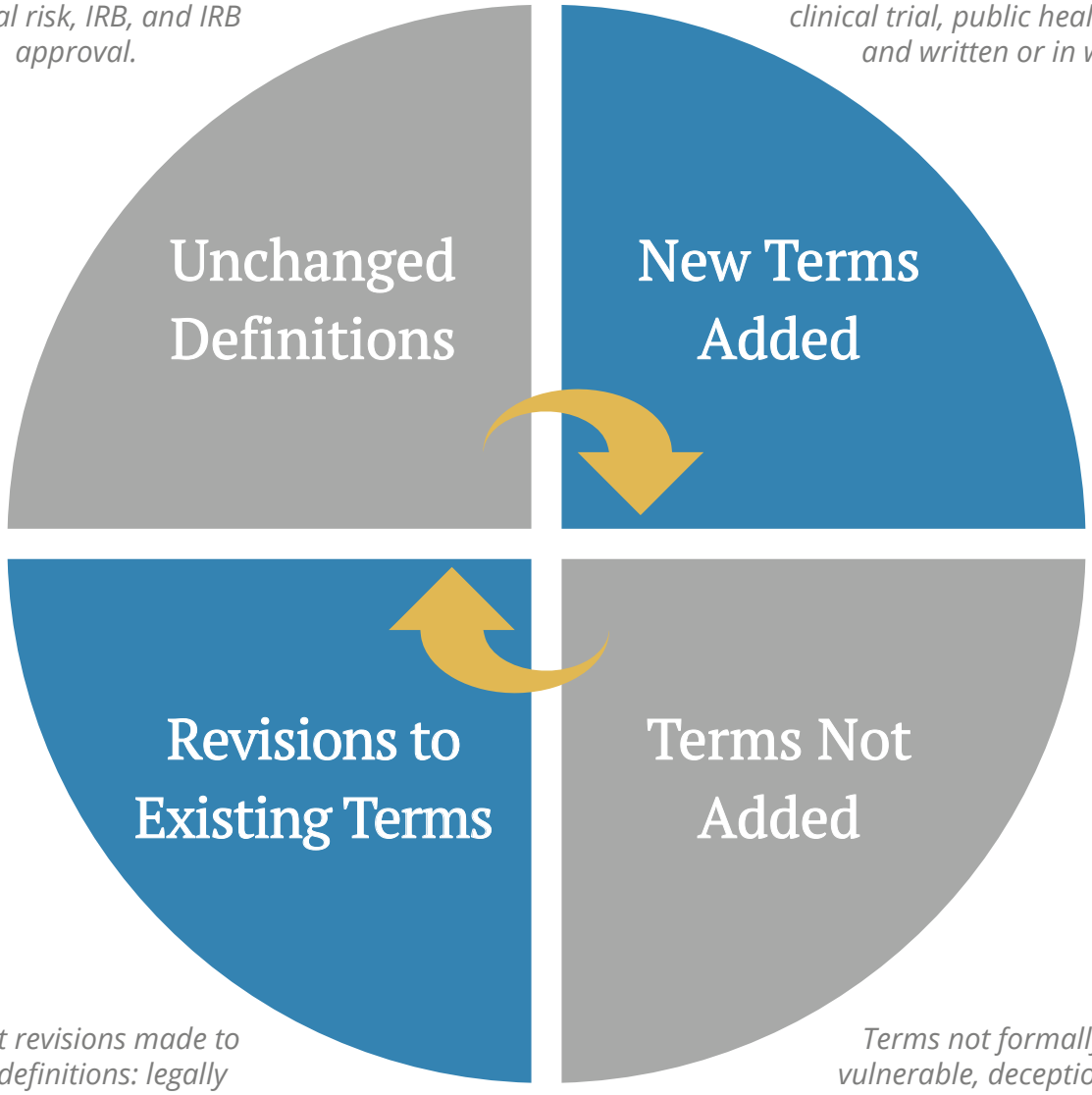
CITI PROGRAM
A division of BRANY

Final Rule
Revisions to Definitions

Unchanged definitions include: minimal risk, IRB, and IRB approval.

New terms defined include: clinical trial, public health authority, and written or in writing.



Significant revisions made to exisiting definitions: legally authorized representative, research, and human subject.

Minor clarifications made to wording: intervention, interaction, private information, and identifiable private information.

Terms not formally defined: vulnerable, deception, sIRB and cooperative research, key information, practicably, broad consent, secondary research use, limited IRB reveiew, and benign behavioral intervention.

Note: the definition of "research" at 46.102(l) of the 2018 requirements is one of the burden-reducing provisions allowed during the delay period (19 July 2018 -20 January 2019).