

NIH Clinical Trial Processes Chart with Reform Dates: Text Version

This graphic depicts the eight-step NIH clinical trial process and associated reforms, including the start dates for the reforms.

The first step in the process is the Idea, followed by Application, Application Review, Funding, IRB Review, FDA Review, Enrollment and Data Collection, and Results.

For seven of the eight steps, the graphic shows the applicable 2017-2018 NIH reform and its start date.

The reform for the first step, or Idea, is “Good Clinical Practice training,” effective January 1, 2017.

Two reforms are shown for the second and third steps, Application and Application Review. The reforms are “clinical trial-specific funding opportunity announcements” and “grant application form changes.” These two reforms are effective for applications with due dates on or after January 25, 2018.

For the fourth step, Funding, no reforms are listed.

The reform for the fifth step, IRB Review, is “single IRB policy,” effective January 25, 2018.

The reform for the sixth step, FDA Review, is “protocol template,” available May 2, 2017.

The reform for the seventh and eighth steps, Enrollment and Data Collection and Results, is “expanded Clinicaltrials.gov registration and results submission policy,” effective January 18, 2017.