

## Identifying an “Applicable Clinical Trial” under FDAAA

- This flowchart presents basic guidance on determining if a trial is considered an “applicable clinical trial” under FDAAA. It maps out the guidance provided in the “[Elaboration of Definitions of Responsible Party and Applicable Clinical Trial](http://grants.nih.gov/ClinicalTrials_fdaaa/index.htm)”, and is also available as an interactive flowchart at: [http://grants.nih.gov/ClinicalTrials\\_fdaaa/index.htm](http://grants.nih.gov/ClinicalTrials_fdaaa/index.htm)
- This flow chart may not address every situation. The grantee’s sponsored research office, general counsel, or other similar official should be involved in determining whether or not the grant supports an applicable clinical trial that needs to be registered under FDAAA.

