Identifying the "Responsible Party" Under FDAAA for Applicable Clinical Trials Conducted Under NIH Grants

- This flowchart presents basic guidance on determining what entity or individual would be considered the "responsible party" under FDAAA for applicable clinical trials conducted under NIH grants (including cooperative agreements). It maps out the guidance provided in the "Elaboration of Definitions of Responsible Party and Applicable Clinical Trial", and is also available as an interactive flowchart at: http://grants.nih.gov/ClinicalTrials_fdaaa/index.htm .
- This flow chart may not address every situation. The grantee institution'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.