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.

```
Does the applicable clinical trial involve an IND/IDE?

No

The grantee institution would generally be considered the sponsor and therefore the responsible party under FDAAA, unless ...

As sponsor, did the grantee institution designate the PI of the trial as the responsible party?

No

The grantee institution would generally be considered the responsible party under FDAAA.

Yes

The designated PI would generally be considered the responsible party under FDAAA.

Yes

The IND/IDE holder would generally be considered the sponsor and therefore the responsible party under FDAAA, unless ...

As sponsor, did the IND/IDE holder designate the PI of the trial as the responsible party?

No

The IND/IDE holder would generally be considered the responsible party under FDAAA.

Yes

Yes

The IND/IDE holder would generally be considered the responsible party under FDAAA.
```