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”, 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’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.

Review the following criteria to determine if the applicable clinical trial (ACT) needs to be registered under FDAAA:

If the trial was initiated after 9/27/2007 ...

If the trial was initiated on or before 9/27/2007 and ongoing as of 12/26/2007 and involves a serious or life threatening disease or condition ...

If the trial was initiated on or before 9/27/2007 and ongoing as of 12/26/2007 and does not involve a serious or life threatening disease or condition ...

If the trial was ongoing as of 9/27/2007, did involve a serious or life threatening disease or condition and was completed (meaning, not ongoing) by 12/26/2007 ...

If the trial was ongoing as of 9/27/2007, did not involve a serious or life threatening disease or condition and was completed (meaning, not ongoing) by 12/26/2007 ...

... then the ACT is not subject to FDAAA, although if it is a drug clinical trial, it may be subject to pre-existing registration requirements under the Food and Drug Administration Modernization Act (FDAMA) of 1997.

... then the ACT is not subject to FDAAA, even if it is a drug clinical trial, it is also not subject to pre-existing registration requirements under FDAMA.

... then the ACT must be registered not later than 21 days after the first patient is enrolled, or by 12/26/2007, whichever is later.

... then the ACT must be registered by 12/26/2007.

... then the ACT must be registered by 9/27/2008.

... then the ACT is subject to section 522 of the FDC Act.