FOOD AND DRUG ADMINISTRATION AMENDMENTS ACT OF 2007 (FDAAA)

FREQUENTLY ASKED QUESTIONS FOR CONTRACTS

1. My IC has a contract supporting the conduct of an applicable clinical trial. Are we considered the initiator and, therefore, the Sponsor of the clinical trial?

**Answer:** In general, yes. Under a contract, the IC is “obtaining goods or services for direct benefit or use under a procurement funding agreement.” As such, and unless another entity holds the IND/IDE or could otherwise be considered the “initiator” of the trial, then the IC is considered the Sponsor and, therefore, the Responsible Party for applicable clinical trial(s) funded through a contract mechanism. If there is an IND/IDE holder, that entity is considered the Sponsor.

1. I am working with my IC contracts specialist on a solicitation that will include an applicable clinical trial. What information, if any, should we include in the solicitation regarding compliance with FDAAA?

**Answer:** The DGS RFP Handbook (available at http://oa-intranet.nci.nih.gov/workforms-set.htm) provides language about FDAAA to include in the solicitation and the contract.

1. My IC has a contract supporting the conduct of an applicable clinical trial. Although we are the initiator and, therefore, the Sponsor of the clinical trial, we would like to designate the Principal Investigator (PI) as the Responsible Party. May we do so? If so, how?

**Answer:** Yes, the PI of the trial may be designated as the Responsible Party as long as the PI can meet the following four conditions established by FDAAA. The PI 1) is responsible for conducting the trial; 2) has access to and control over the data from the clinical trial; 3) has the right to publish the results of the trial; and, 4) has the ability to meet all of the requirements for the submission of clinical trial information.

Instructions and contract language for designating the PI as the Responsible Party are available in the DGS Contract Workform available at http://oa-intranet.nci.nih.gov/workforms-set.htm.

1. My IC is going to fund a multi-site clinical trial. The sites are subcontractors of our Coordinating Center which is a contract to my IC. What entity is the Sponsor? What entity is the Responsible Party for this trial?

**Answer:** Here again, unless another entity holds the IND/IDE or is the initiator of the trial, the IC would generally be considered the “initiator” of the trial under FDAAA, and, as such, the Sponsor under FDAAA. The IC is, thereby, the Responsible Party unless it chooses to designate the PI as the Responsible Party. Four conditions need to be met in order to designate the PI as the Responsible Party (see answer to question 3).

1. My IC holds the IND for an applicable clinical trial being conducted under contract. My IC already transferred the IND sponsor obligations on the IND Application form FDA 1571. Does this transfer of IND sponsor obligations constitute designation of the PI as the Responsible Party (under FDAAA) or does a Responsible Party designation need to be handled separately?

**Answer:** Transferring IND sponsor obligations through FDA 1571 does not include designation of the Responsible Party role under FDAAA. The Responsible Party designation must take place through the contract or contract modification. (Note that form FDA 1571 is not used for IDEs).

Instructions and contract language for designating the Responsible Party are available in the DGS Contract Workform available at http:oa-intranet.nci.nih.gov/workforms-set.htm.

1. What is the responsibility, if any, of the Contracting Officer and the Contracting Officer Technical Representative (COTR) in monitoring a contractor’s compliance with FDAAA if the contractor’s Principal Investigator has been designated the Responsible Party as part of the contract terms and conditions?

**Answer:** When the Sponsor designates the PI as the Responsible Party, the Responsible Party is responsible for complying with registration and results reporting requirements under FDAAA. Further, the Responsible Party is contractually obligated to satisfy these responsibilities and to provide the COTR with the trial registration number (NCT number) subsequent to trial registration in clinicaltrials.gov. The COTR must report any concerns about non-compliance to the Contracting Officer. The COTR may use the NCT number to search clinicaltrials.gov to verify that the trial has been registered and that results have been submitted within the timeframes specified under the statute.