

FINANCIAL CONFLICT OF INTEREST POLICY

Burleson Research Technologies, Inc.
120 First Flight Lane
Morrisville, NC 27560



INTRODUCTION

This policy describes the identification and reporting of actual, apparent, and potential Financial Conflicts of Interest (FCOI), with respect to research projects for which funding is sought or received from the National Institutes of Health (NIH).

Conflicts of Interest would exist if there are conflicting roles that might bias our judgment in the performance of work for the Government, or if BRT obtains an unfair competitive advantage in future procurements as a result of performance of the contract. It is difficult to identify all situations that might involve possible conflicts of interest, but BRT personnel will pay particular attention to any proposed contractual requirements that provide for the rendering of advice, or consultation or evaluation services, or similar activities that lay direct groundwork for Government decisions on future acquisitions, research and development programs, production, or regulatory activities.

BRT management has the responsibility to review for, and avoid and mitigate potential FCOIs for new and existing work and for business development activities.

THE COMPANY

Burleson Research Technologies, Inc. (BRT) is a small business incorporated in the State of North Carolina since 1996 with its corporate headquarters located in Morrisville, NC, adjacent to Research Triangle Park. BRT is a commercial biomedical contract research organization that focuses primarily on immunotoxicology testing of novel therapeutics, chemicals/pesticides and cosmetic constituents. BRT provides laboratory services to clients in the biotechnology, pharmaceutical, chemical manufacturing, and health care industries. Our expert scientific staff delivers solutions with proof-of-concept, preclinical, clinical, and toxicology studies that reflect BRT staff scientific expertise.

FINANCIAL CONFLICTS OF INTEREST - DEFINITION

An *organizational Financial Conflict of Interest* exists, if due to financial investments or holdings of the company:

- The company is unable or potentially unable to render impartial assistance or advice to the Government
- The company's objectivity in performing the contract work is or might be otherwise impaired
- The company has an unfair competitive advantage.

A *personal Financial Conflict of Interest* exists if the relationship of an employee with an entity has the potential to impair the objectivity of the employee in performing the contract work by directly and significantly affecting the design, conduct or reporting of research funding.

BRT recognizes that there is a potential for conflicts of interest or the appearance of conflicts of interest to arise through the performance of work by BRT. It is expected that conflicts of interest exist only in particular cases and circumstances, and not in general situations. However, BRT will promptly disclose to the Project Officer any FCOI.



FCOI EVALUATION

BRT will conduct an FCOI evaluation with respect to research projects for which funding is sought or received from the NIH for any new work, including new work under existing contracts, and when submitting any bid or proposal.

The evaluation will include (1) work related to clients for whom BRT performed work over the past year, (2) the current BRT work, and (3) future BRT work reflected in ongoing marketing proposals. If an actual or potential COI situation is identified, the information will be promptly disclosed to the client, along with measures that can be taken to avoid or mitigate the potential COI situation.

PROCEDURES TO AVOID OR MITIGATE POTENTIAL FCOI

In case of a declared FCOI, procedures will be proposed to avoid or mitigate the potential FCOI. These procedures will be subject to client approval and contract modification, if necessary, before implementation. Proposed procedures may include:

- (1) Establishing separate units containing those workers who conducted past work from those who will be involved with contemplated work.
- (2) Ceasing work for the current client, or if there is a potential for bias to enter into advice, establishing an “independent” Verification and Validation entity, either within the company or through outside entity, to oversee BRT products or performance.
- (3) Turning down either the contemplated or future work or restricting the Company’s involvement in client-sensitive activities on the project
- (4) In case of a personal conflict, the employee in question may be reassigned to other work, placed in a non-decision making role, or required to sign a declaration that he/she will protect the confidentiality of data obtained from the client.

RESPONSIBILITIES

The President and Vice President are primarily responsible for making organizational FCOI determinations for BRT. These responsibilities may be delegated to other personnel to the extent necessary to carry out the FCOI determinations.

All investigators (senior scientific employees) are responsible for completing training every four years, and completing the required FCOI disclosure form yearly, or within 30 days of a change in financial status (acquisition of new financial interest), whichever occurs first

BRT will disclose to the client any and all actual or potential organizational or personal FCOI situations immediately upon identification. The written disclosure will contain a detailed discussion of measures BRT has taken or will take to avoid or mitigate the FCOI. Work will not proceed after such disclosure until BRT receives written approval from the client.

BRT will maintain this documentation in the contract file and/or work assignment file, as appropriate.



TRAINING AND DOCUMENTATION

New employees under this policy will receive a copy of this FCOI plan along with training information. BRT will also periodically disseminate information concerning FCOI issues to its employees through meetings, and memoranda.

Documentation that all senior scientific employees (Study Directors and PIs) have read and understand the contents of the current plan, and completed the appropriate FCOI Disclosure Form will be retained by BRT.

SUBCONTRACTOR COI IDENTIFICATION

BRT will require that each subcontractor/consultant (in roles that can bias BRT's judgement in the performance of the contract) certify it has prepared and is following its FCOI plan, or will complete BRT's Training and FCOI documentation. Each subcontractor/consultant will notify BRT of any actual or potential FCOI and disclose specific FCOI circumstances to the client.

HISTORY OF CHANGE

v.	Effective	Supersedes v.	Reason
1.2	Aug 2016	1.1	> Clarification of yearly (or within 30 days of change) update requirement for investigators > Clarification of training requirement every four years
1.1	Dec 2014	N/A	N/A

