Becton, Dickinson and Company
Policy on Conflicts of Interest Related to Research

This policy defines the obligations of *Investigators* in Becton, Dickinson and Company's research community and governs *Investigators*' financial interests / relationships related to their research when the source of funding is the U.S. Government. The contents of this policy have been designed in accordance with compliance requirements set forth in BD's Code of Conduct and U.S. Government's Financial Conflict of Interest Regulations 42 CFR Part 50 Subpart F (grants and cooperative agreements) and 45 CFR Part 94 (contracts).

1. **Purpose**. The purpose of this policy is to set forth the framework for identifying, evaluating, and managing financial conflicts of interest related to U.S. Government-funded research activities in order to minimize the risk of bias and to maintain integrity, credibility and respect for the work of BD researchers.

2. Applicability. This policy is applicable to all U.S. Government-funded research being conducted by Becton, Dickinson and Company and its worldwide affiliates and subsidiaries ("BD").

3. ***Investigator*** **Disclosure and FCOI Officer Requirements**.[1] [2] Each Investigator must disclose the following Significant financial interests (*SFIs*) (and those of his/her Family members) that reasonably appear to be related to the Investigator's Institutional responsibilities:

☐ For a public *Outside organization*: remuneration for the twelve (12) months preceding the date of the disclosure plus the value of current equity that when aggregated exceed $5,000

☐ For a non-publicly traded *Outside organizat*ion: any equity (regardless of value) and remuneration for the 12 months preceding the date of the disclosure exceeding $5,000

☐ Income from intellectual property rights not assigned to BD

☐ Any *Clinical trial intellectual property*, whether or not assigned to BD

☐ Any *Fiduciary Role in any Outside organization*

[1] The acronym FCOI (for Financial Conflict of Interest) reflects the policy's overall focus on the identification, evaluation and management of financial conflicts of interests.

[2] Defined terms are italicized with selected definitions provided at the end of the overview.

A *financial interest* is related to an *Investigator's Institutional responsibilities* if, for example, it arises from extramural activities that derive from the *Investigator*'s professional standing or are within that *Investigator*'s expertise in his or her professional field(s) of discipline, such as consulting, serving on a scientific advisory board, providing continuing professional education services, or serving as an expert witness for an *Outside organization* that, to the best of the *Investigator*'s knowledge, conducts or seeks to conduct business related to the *Investigator*'s field of discipline. In addition, equity in, or serving in a fiduciary role for, an *Outside organization* that, to the best of the *Investigator*'s knowledge, conducts or seeks to conduct business related to the *Investigator*'s field of discipline, is related to the *Investigator's Institutional responsibilities*.

SFIs do not include the following types of financial interests: salary, royalties, or other remuneration paid by BD to the *Investigator* if the *Investigator* is currently employed or otherwise appointed by BD, including intellectual property rights assigned to BD and agreements to share in royalties related to such rights, income from investment vehicles such as mutual funds and retirement accounts, as long as the *Investigator* does not directly control the investment decisions made in these vehicles; income from seminars, lecture, or teaching engagements sponsored by an *Excluded Payer*, or income from service on advisory committees or review panels for an *Excluded Payer*, or a research institute that is affiliated with an institution of higher education.

Investigators must disclose their *SFIs* at the time of proposal submission, annually, when added as an *Investigator* to an ongoing U.S. Government-funded project, and prior to participation in any U.S. Government-funded research. *Investigators* are also required to timely update (within thirty (30) days) their disclosures in the event of acquiring or discovering new *SFIs* or changes in their previously reported *SFIs*.

Investigators participating in research funded by the U.S. Government must also disclose travel reimbursed or paid on the *Investigator's* behalf with such research funds within the most recent twelve (12) months, other than by an *Excluded Payer*.

Each BD business will appoint an *FCOI Office/Officer* to solicit (as described in Section 4) and review *SFI* disclosures to determine which *SFI*s (if any) are related to the research. The *FCOI Officer* shall be independent of the research being conducted. *Investigators* shall report *SFI* disclosures to the *FCOI Officer* and shall include *Investigator's* assessment of the relationship of the *SFIs* to research in which *Investigator* participates or plans to participate.

The responsibility for disclosing *SFIs* rests with the *Investigator*; however, the *FCOI Officer* shall also solicit and otherwise make *Investigators* aware of their reporting responsibilities in order to ensure that *SFIs* are reported: (i) no later than at the time of application for federally-funded research; (ii) at least annually during the period of the award; and (iii) within thirty (30) days of discovering or acquiring a new *SFI*.

The federal agency may have more stringent financial disclosure requirements than those set forth above. In such cases, *Investigators* shall comply with the requirements set forth in the award document or as otherwise set forth in writing by the agency.

BD shall document roles (e.g., the *FCOI Officer*) for each applicable award in the NIH Electronic Records Administration (eRA) Commons or as required by agency regulations.

4. Assessment of Disclosures for Relatedness to the Research.

The *FCOI Officer* shall assess all *SFI* disclosures for relatedness to the federally-funded research. Assessment will include all *SFIs* reported by *Investigators* and solicited by the *FCOI Officer* pursuant to this Section 4. Review of all such timely submitted Investigator *SFI* disclosures, determination of relatedness to the research, determination of whether the *SFI* is a *FCOI*, and the development and implementation of *Management Plan* (defined below) as needed to manage any *FCOIs*, as set forth below, shall be completed prior to BD's expenditure of agency funds.

The *FCOI Officer* shall assess *SFI* disclosures within sixty (60) days whenever BD identifies an *SFI* that was not disclosed, identified, reviewed, or managed in a timely fashion by an *Investigator*.

The *FCOI Officer* shall also assess *SFIs* submitted by subrecipient *Investigators*, as applicable (see Section 13).

A determination of relatedness to the federally-funded research will be made based on the *Investigator's* and *FCOI Officer's* and BD counsel's assessment, the nature of the research, and/or on other facts deemed relevant by BD.

If the *FCOI Officer* and BD counsel determine that one or more disclosed *SFI*s or travel relates to the research, BD shall direct the *Investigator* to submit information regarding those related *SFI*s to the BD Ethics Office Director (ethics_office@bd.com) for *FCOI* determination.

5. Determination of a Financial Conflict of Interest (FCOI). A *Financial Conflict of Interest* (*FCOI)* is an *SFI* that could directly and significantly affect the design, conduct, or reporting of federally-funded research. BD may utilize several forms of review to reasonably determine whether an *SFI* related to the research is an *FCOI,* and whether an *FCOI* is manageable, including consulting the NIH website relating to *FCOIs* (https://grants.nih.gov/grants/policy/coi/index.htm), the BD Code of Ethics, and BD's corporate Ethics and Compliance officials, depending on the nature and value of the disclosed financial interests, as well as other factors.

BD may be required to disclose *Investigator* information pertaining to *FCOIs* to sponsors and/or

oversight agency and, in some cases, to the public. Such disclosures may contain such details as the value and nature of the *Financial Interest* and elements of the *Management Plan* (described below).

6. Management of FCOIs, including FCOIs Involving Clinical Trials. An *SFI* found to constitute an *FCOI* may be subject to a *Management Plan*, developed by the *FCOI Office/Officer* and/or other BD designee, as a condition to the *Investigator's* participation in the research. The *Management Plan* shall specify the actions that have been, and will be, taken to manage the *FCOI* going forward and shall include the following key elements: (i) the role and principal duties of the conflicted *Investigator* in the research project; (ii) conditions of the *Management Plan*; (iii) how the *Management Plan* is designed to safeguard objectivity in the research project; (iv) confirmation of the *Investigator's* agreement to the *Management Plan*; (v) how the *Management Plan* will be monitored to ensure *Investigator* compliance throughout the research program; and (vi) other information as needed. The determination of whether an *FCOI* is manageable, including an *FCOI* involving a *Clinical Trial*, will take into account the above factors as well as the nature and design of the research and the magnitude and nature of the *financial interest.* With respect to *Clinical Trials*, other relevant factors include the degree of risk to human subjects, the role of the *Investigator* in the study, the study's design, and the degree of the *Investigator's* influence upon the recruitment/ enrollment of subjects and/or the results of the study.

Once the *Management Plan* has been finalized, the *FCOI Officer* will submit, as applicable, *FCOI* reports required by the sponsoring entity and the regulation, including: (i) the name of the entity with which the *Investigator* has an *FCOI*; (ii) the nature and value of the *SFI*; (iii) a description of how the *financial interest relates* to federally-funded research; (iv) why BD determined that the *financial interest* conflicts with such research; (v) key elements of BD's *Management Plan*; and (vi) areas in which the *FCOI* report fails to comply with the *FCOI* regulation (e.g., identification of the *FCOI* in an untimely manner, failure by the *Investigator* to disclose an *SFI*, failure by BD to review or manage an *FCOI*, or failure to comply with BD's *Management Plan*).

7. Retrospective Review.

Retrospective Reviews shall be conducted by BD in order to determine whether any of the funded research, or a portion(s) thereof, conducted during the time period of noncompliance was biased in the design, conduct, or reporting of such research. The *FCOI Officer* and/or other BD designee(s) shall complete and document Retrospective Reviews within one-hundred twenty (120) days of BD's determination of noncompliance for *SFIs* not disclosed in a timely manner or previously reviewed or whenever an *FCOI* is not identified or managed in a timely manner.

BD shall document the results of the Retrospective Reviews consistent with the regulation. Review documentation shall include the award agreement number, project title, project

director/principal investigator or contract project director/principal investigator, name of the *Investigator* having the *FCOI*, name of the entity with which the *Investigator* has an *FCOI*, the reason(s) for conducting the Retrospective Review, a detailed description of the methods used to conduct the Retrospective Review, and the findings and conclusions of the review. If bias is found, BD shall notify the applicable federal agency promptly and submit a Mitigation Report (see below). Should a Retrospective Review reveal new information that changes a previously submitted *FCOI* report (e.g., an increase in value of a previously reported *SFI* or a change in the management of an *FCOI* from what was previously reported under the previously submitted *FCOI* report), BD shall submit a revised report.

In addition, BD shall report to the sponsoring entity and the applicable federal agency if *Investigator's* failure to comply with BD's *FCOI* policy or an *FCOI Management Plan* appears to have biased the design, conduct, or reporting of the federally-funded research.

8. Mitigation Reports. BD shall submit a Mitigation Report through the FCOI Module (see Section 9 – Reporting) in cases where bias is found in the design, conduct or reporting of federally-funded research following a Retrospective Review. Mitigation Reports shall include: (i) key elements documented in the Retrospective Review; (ii) a description of the impact of the bias on the research project; and (iii) a description of BD's plan of action(s) taken to eliminate or mitigate the effect of the bias.

9. Reporting. *FCOI* and Mitigation reports and supporting documentation shall be submitted to the applicable federal funding agency as required by regulation.

FCOI reports shall be submitted as follows and as required by the agency:

- New reports shall be submitted prior to the expenditure of funds under the federally-funded research project
- New reports for an *Investigator* who is newly participating in the research shall be submitted within sixty (60) days of identification
- Revised reports shall be submitted within sixty (60) days of identifying a new *FCOI*
- Updates to a previously-submitted report shall be submitted, if appropriate, following a Retrospective Review to specify the actions that have been, and will be taken to manage the *FCOI* going forward or update previously submitted report.
- Annual reports shall be submitted concurrently with the annual progress report, including a multi-year progress report, or at the time of extension, to provide the status of the *FCOI* and any changes to the *Management Plan*, if applicable, until completion of the project.

10. Training. *Investigators* must successfully complete training from BD related to research-related *FCOI* prior to engaging in U.S. Government-funded research and at least every four years thereafter, and immediately if: (i) BD revises this policy in a way that would affect requirements of the *Investigator; (ii)* the *Investigator* is new to BD; and (iii) the *Investigator* is not in compliance with this policy or BD's *Management Plan*. Training may be provided through BD's online training platform or by the *FCOI Officer*. The *FCOI Officer* shall ensure compliance with the training

schedule. Training shall include an overview of the regulation, this policy, and *Investigator's* responsibilities hereunder. Documentation of *Investigator* training shall be retained by BD.

11. Record Retention. BD shall retain all *FCOI*-related records for the longer of: (i)three years from the date of final expenditures report is submitted to the PHS (NIH); or (ii) from other dates specified in 45 CFR 74.53(b) and 92,.42(b), as applicable. Such records shall be retained by BD.

12. Enforcement Mechanisms and Remedies for Noncompliance.

Investigator sanctions for violations of this Policy shall be considered in accordance with BD's Code of Conduct. Appropriate members of management, to be determined on a case-by-case basis, shall establish the actions to be taken in the event of noncompliance. In the event of a violation by any director of the company or executive officer, the Board of Directors shall make such determination. Any associate who fails to meet the standards of conduct described in this Policy, and any manager or supervisor who attempts to punish an associate for raising questions or trying to follow the principles hereunder, will be subject to discipline. Such discipline shall be reasonably designed to deter wrongdoing and to promote compliance with the Policy and may include, without limitation, corrective actions up to and including termination of the individual's employment.

In any case in which the Department of Health and Human Services determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an *Investigator* with an *FCOI* that was not managed or reported by BD as required by the regulation, BD shall require the *Investigator* involved to: (i) disclose the *FCOI* in each public presentation of the results of the research, and (ii) to request an addendum to previously published papers.

13. Subrecipient Monitoring. As required by the federal agency award or a subaward received through a pass-through entity BD shall require any written subaward agreement with any organization to include terms establishing the applicable *FCOI* policy governing the subrecipient's work, whether it is this BD Policy or that of the subrecipient. Subrecipient will be required to provide written certification that its *FCOI* policy complies with the regulation or, if unable to provide such certification, this BD Policy will be applicable to all subrecipient Investigators. If applicable, BD shall include in the written subrecipient agreement a requirement for the subrecipient to report identified *FCOIs* for its *Investigators* in a timeframe that allows the awardee Institution to report identified *FCOIs* to the federal agency as required by the regulation. Alternatively, if applicable, BD shall include in the written agreement a requirement to solicit and review subrecipient *Investigator* disclosures that enable the awardee Institution to identify, manage, and report identified *FCOIs* to the federal agency.

14. Public Availability and Requests from the Public Regarding *FCOI* Information. BD shall

make this policy available to its employees through BD's intranet and publicly available on its public website. To the extent required by law (e.g., PHS regulations) or otherwise by the terms and conditions of a research award, in response to a written request for information related to *FCOIs* held by *senior/key personnel* of the particular research project specified in the request, BD will provide required information to the requestor. Prior to the expenditure of funds, any identified *FCOIs* held by senior/key personnel (as defined by the regulation) shall be made publicly accessible on BD's public website or made available within five (5) calendar days of receipt of a written request. Such disclosure will include: (i) at minimum, the elements as provided in the regulation; (ii) be updated at least annually, with any response to a written request including the updated information; and (iii) be updated within sixty (60) days of a newly identified *FCOI* (web site only, but any response to a written request should include the updated information); and (iv) remain available for three (3) years from the date the information was most recently updated.

15. Other Policy Provisions. In addition to the foregoing, the *FCOI* Policy includes other provisions as required by law, research sponsors and/or BD. These include *FCOI* disclosure and reporting requirements for sub-awards, the reporting of *FCOIs* to research sponsors (e.g., PHS agencies), as well as provisions to address noncompliance with the *FCOI* Policy.

16. Selected Definitions

Clinical trial shall have the same meaning as prescribed from time to time by the World Health Organization.

Clinical trial intellectual property means an *Investigator*'s interest in intellectual property that is the subject of a copyright, issued patent, or a patent application (regardless of whether the intellectual property has been patented, licensed, or assigned to BD) if such intellectual property is being tested, evaluated, or developed in, or if its commercial value could be affected by, the *Clinical trial* in which the *Investigator* is engaged or proposes to engage.

Excluded payer means a Federal, state, or local government agency, a United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Family member means an *Investigator*'s spouse or dependent child. From to time, the *Institutional official* may amend the definition of *Family member* and notify the BD research community prior to the effective date of such change.

Fiduciary role means membership on the governing board of an entity, including service on its board of directors, or having a position of authority or responsibility to act in the best interest of the entity, including being an officer, manager, partner, or limited liability company member with management responsibility.

Institutional official means the means the BD Ethics Office Director.

Institutional responsibilities means an *Investigator*'s professional or employment-related responsibilities on behalf of BD, which may include research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, whether externally or internally funded, or proposed for such funding, which may include, for example, collaborators or consultants.

Outside organization means any organization other than BD or its corporately-owned entities, and other than an *Excluded payer*.

17. Related BD Programs and Policies

BD's Corporate Ethics and Compliance Office Program
BD Code of Conduct

For questions regarding *FCOI*, please contact BD's Ethics Helpline, at 1-800-821-5452 or by e-mail at ethics_office@bd.com.