

## **FINANCIAL CONFLICTS OF INTEREST POLICY**

### **1. PURPOSE**

1.1. This Policy entitled “Financial Conflicts of Interest Policy” implements Financial Conflicts of Interest (FCOI) disclosure requirements found in 42 CFR Part 50, Subpart F, “Promoting Objectivity in Research” and 45 CFR Part 94, “Responsible Prospective Contractors” which are applicable to Research funded by the U.S. Public Health Service (PHS). These requirements are applicable to all Research projects for which D2G Oncology, Inc. (“D2G”) applies, or receives, Research funding from PHS, except for Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Program Phase 1 applications. SBIR is the extramural research program for small business that was established by the Awarding Components of PHS and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. The term SBIR Program includes the STTR Program, which was established by Pub. L. 102-564.

1.2. This Policy is intended to ensure objectivity in which Research projects are designed, conducted, or reported by managing any FCOI that occurs between an Investigator’s personal financial interests and their professional interests with respect to Research conducted with PHS funding. This Policy establishes a process of disclosure and independent review when an Investigator has a FCOI. If D2G determines that such an FCOI might reasonably appear to affect the Research directly and/or significantly, D2G will develop a mitigation plan to manage or eliminate the conflict in accordance with this Policy.

### **2. SCOPE**

2.1. Each Investigator, as defined in the Policy, who will participate, or is participating, in such Research, must follow this Policy and complete the required training. Subcontractors and consultants who perform services within the definition of an Investigator must either maintain a policy that complies with the requirements of 42

CFR Part 50, Subpart F and 45 CFR Part 94 or comply with this Policy. Questions and concerns regarding this Policy should be directed to the D2G IO.

### **3. DEFINITIONS**

3.1. **D2G’s Institutional Official (“D2G IO”)** is an official designated by D2G to solicit and review completed Disclosure Forms from each Investigator who is planning to participate in, or who is participating in, PHS funded Research and to determine whether any reported SFI is a FCOI. References to the D2G IO in this document include their delegate.

3.2. **Financial Conflict of Interest (“FCOI”)** is a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct or reporting of PHS funded Research.

3.3. **“Financial interest”** means anything of monetary value, whether or not the value is readily ascertainable.

3.4. **“Institutional Responsibilities”** means an Investigator’s professional responsibilities performed on behalf of D2G, and as defined by D2G in this Policy, which may include for example: activities such as research, research consultation, teaching, professional practice, committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

3.5. **“Investigator”** is any individual, regardless of title or position, who is responsible for the design, conduct, or reporting of Research funded by the PHS, or proposed such funding, including investigators, consultants, and subcontractors.

3.6. **“PD/PI”** means a project director or principal investigator of a PHS-funded Research project; the PD/PI is included in the definitions of Senior/Key Personnel and Investigator.

3.7. **“PHS Awarding Component”** means the organizational unit of the PHS that funds the Research.

3.8. **“Research”** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research as well as product development (e.g., a diagnostic test or drug) and includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

3.9. **“Senior/Key Personnel”** means the PD/PI and any other person identified as senior or key personnel staff by D2G in the grant application, proposal or any other report submitted to the PHS Awarding Component.

3.10. **Significant Financial Interest (“SFI”)** means the following:

3.10.1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator’s Institutional Responsibilities:

3.10.1.1. With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, warrant, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

3.10.1.2. With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock option, warrant, or other ownership interest); or,

3.10.1.3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

3.10.2. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional Responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

3.10.3. The term SFI does not include the following types of financial interests: salary, royalties, or other remuneration paid by D2G to the Investigator if the Investigator is currently employed by D2G, including intellectual property rights assigned to D2G and agreements to share in royalties related to such rights; any ownership interest in D2G held by the Investigator; 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, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

3.11. **Small Business Innovation Research (“SBIR”)** Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program also includes the **Small Business Technology Transfer (“STTR”)** Program, which was established by Public Law 102-564.

## **4. TRAINING REQUIREMENTS**

4.1. D2G will inform each Investigator of D2G's FCOI policy and each Investigator's disclosure responsibilities in accordance with 42 CFR 50.604(b).

4.2. Each Investigator must complete training prior to engaging in PHS funded research. Acceptable forms of training include, but are not limited to, the NIH Office of Extramural Research FCOI online tutorial (located at: [grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.html](https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.html)) or other training courses approved by D2G.

4.3. Investigators must complete training at least every four years and must immediately complete training under the following circumstances:

4.3.1. D2G's FCOI policy changes in a manner that affects the requirements of Investigators;

4.3.2. An Investigator is new to D2G; or,

4.3.3. D2G determines that an Investigator is not in compliance with D2G's FCOI policy or management plan.

## **5. DISCLOSURE REQUIREMENTS**

5.1. Each Investigator who is planning to participate in PHS funded Research is required to disclose to D2G any SFIs, including any SFI of their spouse or dependent children, no later than the time of application for PHS funded Research.

5.2. Each Investigator who is participating in the PHS-funded Research is required to submit an updated disclosure of SFIs (including any SFI of their spouse or dependent children): (1) at least annually, in accordance with the specific time period prescribed by D2G, during the period of the award; and, (2) within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

5.3. If an Investigator does not have any SFIs to report, the Investigator must still complete the Disclosure Form both initially and annually. Each Investigator must do so by completing the Disclosure Form provided by D2G to the D2G IO. The D2G IO shall solicit and review all required Disclosure Forms and determine whether any reported SFI is a FCOI.

5.4. D2G shall ensure applicable staff comply with these disclosure obligations. Failure to comply with these disclosure obligations may result in disciplinary action by D2G.

## **6. REVIEW AND MANAGEMENT REQUIREMENTS**

6.1. An Investigator's SFI is related to PHS-funded Research when D2G, through the D2G IO, reasonably determines that the SFI: could be affected by the PHS-funded Research; or is in an entity whose financial interest could be affected by the Research. D2G may involve the Investigator in the D2G IO's determination of whether a SFI is related to the PHS-funded Research. A FCOI exists when D2G, through the D2G IO, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded Research.

6.2. The D2G IO will take actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator pursuant to this Policy. Management of an identified FCOI requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report pursuant to this Policy.

6.3. **Review Requirement:** Prior to D2G's expenditure of any funds under a PHS funded Research project, the D2G IO will review all Disclosure Forms with SFIs to determine whether the SFIs relate to the PHS funded Research and whether a FCOI exists. If a FCOI exists, the D2G IO will develop and implement a management plan that specifies the actions that have been, and will be, taken to manage such FCOI. Examples of conditions or restrictions that may be imposed to manage a FCOI include, but are not limited to the follow actions:

6.3.1. Public disclosure of the FCOI (e.g., when presenting or publishing research);

6.3.2. For Research projects involving human subjects, disclosure of the FCOI directly to participants;

6.3.3. Appointment of an independent monitor capable of taking measures to protect the design, conduct and reporting of the Research against bias resulting from the FCOI;

6.3.4. Modification of the research plan;

6.3.5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research;

6.3.6. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or,

6.3.7. Severance of relationships that create financial conflicts.

**6.4. Disclosure and Identification of SFI:** Whenever, in the course of an ongoing PHS funded Research project: (1) an Investigator who is new to participating in the Research project discloses a SFI; (2) an existing Investigator discloses a new SFI; or (3) D2G identifies a SFI that was not disclosed timely by an Investigator or was not previously reviewed by D2G during an ongoing PHS funded Research project, the D2G IO within sixty (60) days of the disclosure will review the SFI to determine whether it is related to PHS funded Research and whether a FCOI exists. If a FCOI exists, the D2G IO will develop and implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage such FCOI. Depending on the nature of the SFI, D2G may determine that additional interim measures are necessary regarding the Investigator's participation in the PHS funded Research project between the date of disclosure and the completion of D2G's review.

#### **6.5. Retrospective Reviews:**

6.5.1. Whenever D2G identifies a SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by D2G during an ongoing PHS-

funded research project (e.g., was not timely reviewed or reported by a subrecipient), the D2G IO shall, within sixty (60) days: review the SFI; determine whether it is related to PHS-funded research; determine whether a FCOI exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward.

6.5.2. In addition, whenever a FCOI is not identified or managed in a timely manner including failure by the Investigator to disclose a SFI that is determined by the D2G IO to constitute a FCOI; failure by the D2G IO to review or manage such a FCOI; or failure by the Investigator to comply with a FCOI management plan, D2G shall, within one hundred twenty (120) days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded Research to determine whether any PHS-funded Research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such Research. D2G is required to document the retrospective review.

Documentation shall include all of the following key elements:

6.5.2.1. Project number;

6.5.2.2. Project title;

6.5.2.3. PD/PI or contact PD/PI if a multiple PD/PI model is used;

6.5.2.4. Name of the Investigator with the FCOI;

6.5.2.5. Name of the entity with which the Investigator has a FCOI;

6.5.2.6. Reason(s) for the retrospective review;

6.5.2.7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);

6.5.2.8. Findings of the review; and,



#### 6.5.2.9. Conclusions of the review.

6.5.3. Based on the results of the retrospective review, D2G will update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, D2G will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. Minimally, the mitigation report must include the key elements documented in the retrospective review, a description of the impact of the bias on the Research project, and D2G's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the Research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the Research project is salvageable). Thereafter, D2G will submit FCOI reports annually. Depending on the nature of the FCOI, D2G may determine that additional interim measures are necessary regarding the Investigator's participation in the PHS funded Research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of D2G's retrospective review.

6.6. **Monitoring:** Whenever D2G implements a management plan, D2G will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS funded Research project.

## 7. REPORTING OF FINANCIAL CONFLICTS OF INTEREST

7.1. **Initial FCOI Report:** Prior to D2G's expenditure of any funds under a PHS funded Research project, D2G will provide to the PHS Awarding Component a FCOI report regarding any Investigator's SFI found by D2G to be a FCOI. Additionally, D2G will ensure that it has implemented a management plan in accordance with this Policy. In cases in which D2G identifies a FCOI and eliminates it prior to the expenditure of PHS awarded funds, D2G is not required to submit a FCOI report to the PHS Awarding Component.

7.2. **Subsequent FCOI Reports:** For any SFI that D2G identifies as a FCOI subsequent to D2G's initial report during an ongoing PHS funded Research project, D2G will provide to the PHS Awarding Component a FCOI report regarding the FCOI within sixty

(60) days of identification of the FCOI. Additionally, D2G will ensure that it has implemented a management plan in accordance with this Policy and, if required, complete a retrospective review and a mitigation report according to this Policy.

**7.3. Contents of a FCOI Report:** Any FCOI report required under this Policy will include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the FCOI and to assess the appropriateness of D2G's management plan. The FCOI report will include the following minimum information:

7.3.1. Project number;

7.3.2. PD/PI or Contact PD/PI if a multiple PD/PI model is used;

7.3.3. Name of the Investigator with the FCOI;

7.3.4. Name of the entity with which the Investigator has a FCOI;

7.3.5. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);

7.3.6. Value of the financial interest (dollar ranges are permissible: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot readily be determined through reference to public prices or other reasonable measures of fair market value;

7.3.7. A description of how the financial interest relates to the PHS funded Research and the basis for D2G's determination that the financial interest conflicts with such Research; and,

7.3.8. A description of the key elements of D2G's management plan including the following minimum information:

7.3.8.1. Role and principal duties of the conflicted Investigator in the Research project;

7.3.8.2. Conditions of the management plan;

7.3.8.3. Explanation of how the management plan is designed to safeguard objectivity in the Research project;

7.3.8.4. Confirmation of the Investigator's agreement to the management plan; and,

7.3.8.5. Explanation of how the management plan will be monitored to ensure Investigator compliance.

**7.4. Annual FCOI Report:** For any FCOI previously reported by D2G regarding an ongoing PHS funded Research project, D2G will provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS funded Research project. The annual FCOI report will specify whether the FCOI is still being managed or explain why the FCOI no longer exists. D2G will provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

## **8. ENFORCEMENT**

8.1. If the failure of an Investigator to comply with this Policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS funded Research, D2G is required to promptly notify the PHS Awarding Component of the corrective action taken or to be taken by D2G. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to D2G for further action, which may include directions to D2G on how to maintain appropriate objectivity in the PHS funded Research project.

8.2. Failure by D2G staff to comply with this Policy may be grounds for disciplinary action up to and including termination.

8.3. In any case in which the HHS determines that a PHS-funded 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 a FCOI that was not managed or reported by D2G as required by this subpart, D2G shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

## **9. RECORD RETENTION**

9.1. Records regarding Disclosure Forms, determinations made by the D2G IO, and D2G's actions regarding management of a FCOI will be retained by D2G for three years beyond the date of the final expenditure report submitted to the PHS Awarding Component under an award or, where applicable, from other dates specified in 45 CFR 75.361, where applicable.

## **10. SUBCONTRACTORS AND CONSULTANTS**

10.1. Subcontractors/consultants who perform services within the definition of an Investigator must maintain a policy that complies with the aforementioned regulatory requirements or comply with this Policy. All applicable subcontract/consulting agreements must contain a clause that requires compliance with the applicable federal regulations either through a policy maintained by the subcontractor/consultant or this Policy. Examples of appropriate clauses are shown below:

### **Financial Conflicts of interest – Compliance with Subcontractor's Policy**

*Subcontractor agrees to comply with any and all requirements relating to Public Health Service funded projects. Without limiting the generality of the foregoing, Subcontractor, its employees and agents agree to comply with the applicable requirements of 42 CFR Part 50, Subpart F and 45 CFR Part 94. Subcontractor certifies that it maintains a policy that requires compliance with these requirements. Subcontractor shall report all identified financial conflicts of interests to D2G immediately and submit a mitigation plan for D2G's review and approval. D2G is under no obligation to approve a mitigation plan. D2G reserves the right to terminate this Agreement or request removal of Subcontractor's employee or lower tier subcontractor as a result of Subcontractor, its*

*employee, or lower tier subcontractor's financial conflict of interest. Subcontractor must include this clause in its agreements with any applicable lower tier subcontractors or consultants. Failure to comply with these requirements is a material breach of this Agreement.*

### **Financial Conflicts of interest – Compliance with D2G's Policy**

*Subcontractor agrees to comply with any and all requirements relating to Public Health Service funded projects. Without limiting the generality of the foregoing, Subcontractor, its employees and agents agree to comply with the applicable requirements of 42 CFR Part 50, Subpart F and 45 CFR Part 94. Subcontractor agrees to comply with D2G's Policy on Financial Conflicts of Interest in Public Health Service Funded Research. Subcontractor shall report all identified financial conflicts of interests to D2G immediately and submit a mitigation plan for D2G's review and approval. D2G is under no obligation to approve a mitigation plan. D2G reserves the right to terminate this Agreement or request removal of Subcontractor's employee or lower tier subcontractor as a result of Subcontractor, its employee, or lower tier subcontractor's financial conflict of interest. Subcontractor must include this clause in its agreements with any applicable lower tier subcontractors or consultants. Failure to comply with these requirements is a material breach of this Agreement.*

## **11. PUBLIC ACCESSIBILITY**

11.1. Prior to D2G's expenditure of any funds under a PHS funded Research project, D2G shall ensure public accessibility by posting to a publicly accessible website information, or written response to any requestor within five (5) business days of a request, concerning any SFI disclosed to D2G that is: (a) held by Senior/Key Personnel performing services for the Research, (b) related to the PHS funded research, and (c) determined by D2G to be a FCOI. The following information regarding the FCOI must be posted to the website:

11.1.1. Project number;

11.1.2. Name of the Investigator with the FCOI, title, and role with respect to the Research project;

11.1.3. Name of the entity with which the Investigator has a FCOI;

11.1.4. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);

11.1.5. Value of the financial interest (dollar ranges are permissible: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot readily be determined through reference to public prices or other reasonable measures of fair market value;

11.2. This information must be updated at least annually as well as within sixty (60) days of either: (a) D2G's receipt or identification of information concerning any additional SFI of the Senior/Key Personnel for the PHS funded Research project that was not previously disclosed; or, (b) upon disclosure of any SFI of Senior/Key Personnel new to the PHS funded Research project and meeting the disclosure criteria. The website shall note that the information is current as of the date shown and is subject to the required updates. Any SFI posted to the Website shall remain available for at least three years from the date that the information was most recently updated by D2G. If D2G responds to written requests for the purposes of this subsection, D2G will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within sixty (60) days of the D2G IO's identification of a new FCOI, which should be requested subsequently by the requestor. All disclosures or information obtained in reviewing a potential FCOI is kept confidential, except where disclosure is required by federal regulations.