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1. **APPLICABILITY: WHO MUST COMPLY WITH THE INVESTIGATOR CONFLICT OF INTEREST POLICY**

This Investigator Conflict of Interest Policy (COI Policy) policy applies to all individuals who fit the definition of Investigator in Section 2 below, including, without limitation, Chief Scientific Officer, Medical Director or any individual identified by DARÉ BIOSCIENCE, INC. (otherwise referred to as the "**Company**") as senior/key personnel in a grant application, progress report, or any other report submitted to a federal funding agency, and also may include Subrecipients, collaborators, consortium members, consultants or subcontractors.

2. **DEFINITIONS**

1. ***Conflict Review Officer (CRO)*** is an administrative representative of the administration who will review Investigator disclosures of Significant Financial Interests (SFIs), determine whether a Financial Conflict of Interest (FCOI) exists, and, if so, develop a management plan for the Investigator to manage, reduce or eliminate the FCOI.
2. ***Financial Conflict of Interest (FCOI)*** will be deemed to exist when the Company's CRO reasonably determines that a significant financial interest disclosed by the Investigator could directly and significantly affect the design, conduct or reporting of Federally Funded Research as defined below with the exception of research funded through Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (SBTT) programs. Note: Phase II SBIR and STTR programs are not exempt like Phase I and are subject to this policy.
3. ***Federally Funded Research*** means any Research funded by a Public Health Service (PHS) awarding component, such as the National Institutes of Health (NIH), National Science Foundation (NSF), Department of Defense (DOD), Department of Energy (DOE) or other U.S. federal agency.
4. ***Investigator*** refers to the Principal Investigator or Project Director, and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of Federally Funded Research or Research that is proposed for federal funding. *Investigators* could include the Chief Scientific Officer, Medical Director or any individual identified by the Company as senior/key personnel in a grant application, progress report or any other report submitted to a federal funding agency, and also may include Subrecipients, collaborators, consortium members, consultants or subcontractors.
5. ***Investigator's Institutional Responsibilities*** means professional activities taking place on behalf of the Company including, but not limited to, Research, Research

consultation, teaching, institutional committee memberships and service on committees or panels such as Institutional Review Boards or other monitoring boards.

6. **Management** of an FCOI means acting to address the FCOI, including the reduction or elimination of conflict so that the Company can reasonably expect that the Investigator's design, conduct and reporting of Research will be free from bias.
7. **Management Plan** is a written document approved by the CRO under which an Investigator with an identified FCOI must take steps and follow guidelines, conditions and/or restrictions to reduce or eliminate the conflict.
8. **Research** means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health or agriculture, and encompasses basic and applied Research. Research includes any activity for which research funding is available regardless of the source, such as research grants, program project or infrastructure award.
9. **Significant Financial Interest (SFI)** means anything of monetary value that was received from an entity in the twelve (12) months preceding the disclosure, whether or not the value is readily ascertainable, belonging to the Investigator, his or her spouse, and/or his or her dependent children, alone or in combination, that reasonably appears to be related to the Investigator's Institutional Responsibilities.
10. **Small Business Innovation Research (SBIR)** is an award designed to support projects from small businesses having commercial viability.
11. **Small Business Technology Transfer (SBTT)** is a program under the SBIR program designed to foster technology innovation through cooperative efforts between small businesses and research institutions.
12. **Subrecipient** refers to an individual or entity that receives federal funds from or through the Company, as an awardee institution, where the subrecipient will be conducting a substantive portion of the Federally Funded Research and who will be accountable to the awardee institution for, e.g., programmatic outcomes and compliance matters.

3. **PURPOSE OF THE INVESTIGATOR CONFLICT OF INTEREST POLICY**

The COI Policy implements and ensures compliance with the specific federal requirements set forth in the United States Department of Health and Human Services' 2011 Objectivity in Research Regulations (COI Regulations), [42 CFR part 50 subpart F](#) (grants) and [42 CFR part 94](#)

(contracts). The COI Regulations establish new standards and clarify previously established standards to be followed by institutions that apply for or receive Research funding from the United States Public Health Service (PHS) Awarding Components, including the National Institutes of Health (NIH), for grants, cooperative agreements, and research contracts.

The Company has the responsibility under the COI Regulations to manage Financial Conflicts of Interest between an Investigator's (and his/her spouse's and dependent children's) personal financial interests and his/her Institutional Responsibilities. The Company and its Investigators must identify, and then manage, reduce or eliminate, FCOIs to strengthen accountability and transparency, promote Research objectivity, maintain the integrity of Research findings, and ensure prudent stewardship of public funds.

4. MANDATED CONFLICT OF INTEREST TRAINING FOR ALL INVESTIGATORS

All Investigators must be informed of the Company's COI Policy as well as their disclosure responsibilities and other requirements of the COI Regulations. The COI Regulations require all Company Investigators to complete a COI training tutorial prior to engaging in Federally Funded Research and at least every four years thereafter. In addition, training is required immediately under the following circumstances:

1. Company revises its policy in a manner that affects the requirement for Investigators with regard to financial interests;
2. An Investigator is a new Company employee; and
3. The Company finds that an Investigator is non-compliant with the Company's COI Policy or management plan.

The Company's training program will be available online, on the Company's intranet. Each Investigator must certify his/her completion after each training session.

5. WHAT CONSTITUTES A SIGNIFICANT FINANCIAL INTEREST (SFI)

An SFI is 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:

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.
 - Remuneration includes salary and any payment for services not otherwise identified as salary such as consulting fees, honoraria and paid authorship.
 - Equity interests include stocks, stock options, or other ownership interests, as

determined through reference to public prices or other reasonable measures of fair market value.

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 (12) 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.
 - Equity interests include stocks, stock options, or other ownership interests including any equity in a non-publicly traded company.
 - The Investigator must fully describe the nature of the equity interest including the number of shares owned, voting rights, etc. if at the time of disclosure there is no reasonable basis for assessing the fair market value or percentage interest in the non-publicly traded entity.
3. Remuneration from **intellectual property rights** such as patents, copyrights and royalties from such rights and agreements to share royalties related to intellectual property rights and interests, not received from the Company.
4. **Travel.** Investigators must disclose the occurrence of any reimbursed or sponsored travel (i.e., travel that is paid on behalf of the Investigator and not reimbursed to the Investigator so the exact monetary value may not be readily ascertainable) that is related to their Institutional Responsibilities and reimbursed or sponsored by any entity *other than* the Company or a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or another research institute that is affiliated with an institution of higher education including the Company. The disclosure must include the following details: the purpose of the trip; the identify of the sponsor/organizer; the destination of the trip; and the duration of the trip.

The Company will then determine if any travel requires further investigation, including determination or disclosure of the monetary value in order to determine whether the travel constitutes a FCOI.

An SFI does not include the following types of financial interests:

1. Salary, royalties, or other remuneration received from the Company if the Investigator is currently employed or appointed by the Company.
2. Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education.
3. Income from service on advisory committees or review panels for a federal, state or local government agency, an institution of higher education, an academic teaching

- hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
4. Travel expenses that are reimbursed or sponsored by the Company or a federal, state or local government agency, an Institution of higher education, an academic teaching hospital, a medical center or another research institute that is affiliated with an institution of higher education.
 5. An equity interest that when aggregated for the Investigator and the immediate family, meets both the following tests:
 - Does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value.
 - Does not represent more than a five (5) percent ownership interest in any single entity.
 6. Salary, royalties or other payments that when aggregated for the Investigator and the immediate family over the next twelve (12) months are not expected to exceed \$5,000.
 7. Intellectual property rights assigned to the Company and unlicensed intellectual property that does not generate income.
 8. Agreements with the Company to share in royalties related to such rights.
 9. 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.

Many scientific journals have implemented policies that require authors to declare competing financial interests in relation to work published in those journals. Such requirements of third parties, including how financial interests are defined, are distinct from the requirements in this policy relating to Federally Funded Research and should not be used as guidance for the information an Investigator must disclose under this policy.

6. SUBMITTING AND UPDATING ANNUAL DISCLOSURE FORMS

All individuals who fit the definition of Investigator in Section 2 above must submit an Annual Disclosure Form at the beginning of their time at the Company and each subsequent year thereafter. All Investigators are required to complete a current, accurate Annual Disclosure Form that identifies and describes both existing and new SFIs. Annual Disclosure Form must be submitted by way of a portal located on the Company's intranet by the yearly December 31 deadline. In addition, Investigators have an ongoing obligation to promptly update their Annual Disclosure Forms to accurately reflect any significant change in their external activities, SFIs, and internal responsibilities as follows:

1. No later than at the time of application for federally funded Research;

2. Within thirty (30) days of discovering or acquiring a new SFI (including through purchase, marriage, or inheritance); and
3. At least annually in accordance with the December 31 deadline.

The Company (i) may not submit any new grant applications to a federal agency for Research projects, and (ii) may not spend any federal funds in connection with Notices of Award for new or continuing Federally Funded Research projects, until all Investigators identified to work on such projects have completed the training and submitted their disclosures as required by the COI Regulations and this policy.

7. ANNUAL DISCLOSURE FORM REVIEW BY THE CRO

The Conflict Review Officer (CRO) will initially review the Annual Disclosure Forms and may request further information or clarification about an SFI. The CRO may be the Chief Financial Officer, President, CEO or other representative as assigned by the Company. The CRO will review all disclosures of SFIs and make a preliminary determination whether any SFI appears to relate to the Research and, if so, whether the SFI may be an FCOI. The CRO reviews and analyzes the specific circumstances of an SFI by taking into account such factors as the nature of the Investigator's relationship to an outside entity, the dollar value of that relationship, and the degree and nature of any overlap between that relationship and the Investigator's Research. The CRO may, if warranted, involve additional Company employees or advisors in determining whether an SFI is related to the Research in question. An FCOI will be deemed to exist when the CRO reasonably determines that an SFI disclosed by an Investigator could directly and significantly affect the design, conduct or reporting of the Investigator's Research.

The steps set forth in this Section 7 must be completed promptly following disclosure of an SFI in order to enable any FCOIs to be reported to the federal funding agency within the sixty (60) day deadline set forth in the COI Regulations and Section 10 of this policy.

8. MANAGING, REDUCING, OR ELIMINATING A FINANCIAL CONFLICT OF INTEREST

If an SFI is identified by the CRO as an FCOI, the CRO will develop a Management Plan to manage, reduce, or eliminate the conflict. The Management Plan will be set forth in a written document and may require the Investigator to take certain steps and follow guidelines approved by the CRO.

As appropriate, the CRO may meet with the Investigator and/or appoint a Company official to meet with the Investigator during the design and development of a Management Plan that will include mechanisms appropriate for the specific situation. The CRO may, as necessary, query other Company committees and/or personnel to solicit alternate ideas for Management of the conflict.

A copy of the Management Plan will be sent by the CRO to the Investigator and to the Company's President, who will have final authority to determine whether an FCOI exists and the

appropriate plan for managing the FCOI. The Investigator may appeal the CRO's proposed Management Plan (or the findings on which the plan is based) to the President within ten (10) calendar days of the date of the plan. The President and/or the CRO may consult with members the Company Board of Directors as needed regarding the FCOI and its Management. After the Management Plan and its implementation schedule have been finalized, the CRO will forward the final version to the Investigator. The Investigator will then review and sign the plan to acknowledge his or her commitment to compliance.

9. REPORTING THE FINANCIAL CONFLICT OF INTEREST TO THE FUNDING AGENCY

1. With regard to a **new Federally Funded Research award**, the CRO will disclose through the eRA Commons FCOI Module required information about the identified FCOI **before the Company spends any awarded funds**. If the FCOI is eliminated prior to spending any funds, then no FCOI report is required. In addition, the Company may be required to submit an FCOI report for FCOIs identified for subrecipient investigators (if applicable) under Section 16 of this policy.
2. With regard to an **ongoing Federally Funded Research award**, the CRO will disclose through the eRA Commons FCOI Module information about the identified FCOI within sixty (60) days of the identification of the FCOI. For any SFI that is identified as an FCOI subsequent to the Company's initial FCOI report during an ongoing Federally Funded Research project, the Company shall implement, within sixty (60) days, on at least an interim basis, a Management Plan that shall specify the actions that have been and will be taken to manage the FCOI.
3. With regard to a **period of non-compliance during an ongoing Federally Funded Research project**, the Company will within sixty (60) days of the Investigator's delayed disclosure of an SFI, determine if the SFI constitutes an FCOI. If the FCOI exists, the Company will implement, on at least an interim basis, a Management Plan that shall specify the actions that have been and/or will be taken to reduce or eliminate the FCOI, and the CRO will submit the FCOI report through the eRA Commons FCOI Module. In addition to the FCOI report, the Company will, within one-hundred twenty (120) days of its determination of non-compliance, complete a retrospective review of the Investigator's activities, and the Research project to determine whether part or all of the Research conducted during the period of non-compliance was biased in the design, conduct or reporting of such Research. Based on the results of the retrospective review, if appropriate, the CRO will update the previously submitted FCOI report, specifying the actions that will be taken to reduce or eliminate the FCOI.
4. With regard to a **new, non-federal award entity**, the Company may, if warranted, disclose to such entity (e.g., corporation, educational institution, nonprofit entity,

private foundation, trust or individual donor) information about an identified FCOI before dispersing or spending any funds and/or during the duration of the award.

5. Annual FCOI follow-up reports will be provided by the CRO to the funding agency for any FCOI previously reported by the Company. The annual FCOI report will specify whether the FCOI is still being managed, describe any changes to the Management Plan or explain why the FCOI no longer exists. The Company will provide annual FCOI reports to the funding agency for the duration of the project period, including extensions with or without funds, at the same time as the Company's Grants Administration department submits the annual progress report or at the time of project extension.

10. WHAT INFORMATION ABOUT AN IDENTIFIED FINANCIAL CONFLICT OF INTEREST IS SUBMITTED TO THE FUNDING AGENCY

Information submitted to a federal funding agency about the identified FCOI shall include the following:

- A description of the key elements of the Company's Management Plan must also be submitted to the funding agency including the following information:
- Grant/contract number
- Name of the principal investigator or project director
- Name of the Investigator with the FCOI
- The name of the entity with which the Investigator has a FCOI Statement about whether the FCOI was managed, reduced or eliminated
- The nature of the FCOI, i.e. equity, consulting fees, travel reimbursement, honoraria
- The value of the financial interest; \$0-\$4,999, \$5,000-\$9,999, \$10,000-\$19,000; amounts between \$20,000-\$100,000 by increments of \$20,000;
- Amounts above \$100,000 by increments of \$50,000
- A statement when a value cannot be readily determined through reference to public prices or reasonable measures of fair market value
- A description about how the FCOI relates to the Research and the basis for the Company's determination that a SFI conflicts with such Research

11. PUBLIC ACCESSIBILITY TO THE COMPANY'S INVESTIGATOR CONFLICT OF INTEREST POLICY AND IDENTIFIED FINANCIAL CONFLICT OF INTERESTS

The Company's COI Policy will be publicly accessible on its website (www.darebioscience.com). In addition, non-compliance with the COI Regulations, the Company will make the following information about identified FCOIs available by written response within five (5) days of a request:

- The name of the Investigator
- The title and role of the Investigator with respect to the Research project
- Name of the entity in which the SFI is held

- The nature of the SFI
- Approximate value of the SFI as determined by dollar range from \$0-\$4,999;
- \$5,000-\$9,999; \$10,000-\$19,000;
- Amounts between \$20,000-\$100,000, by increments of \$20,000; amounts above \$100,000, by increments of \$50,000; or
- A statement when a value cannot be readily determined through reference to public prices or reasonable measures of fair market value

12. CONTINUED MONITORING OF THE FINANCIAL CONFLICT OF INTEREST AND THE COMPANY'S COMPLIANCE

The Company will monitor the FCOI and Investigator compliance with the FCOI Management Plan until the completion of the Research project. As necessary, the CRO may require and develop a project specific monitoring process, which may include appointing a Company designated official to assist with monitoring the FCOI and Investigator compliance. The CRO may modify an Investigator's Management Plan at any time.

13. WHAT HAPPENS AFTER THE FCOI IS REPORTED TO THE FEDERAL AGENCY

The federal agency will evaluate the FCOI information received through the eRA Commons FCOI Module to determine if the Company's actions are sufficient enough to reduce or eliminate the identified FCOI. The federal agency may request and review additional information before implementing (if needed) further corrective actions to ensure research objectivity. If the federal agency decides that the particular FCOI will bias the objectivity of the funded Research to such an extent that further corrective action is needed or that the Company has not managed the FCOI in accordance with the regulation, it may impose special award conditions, suspend funding or enforce other actions until the matter is sufficiently resolved.

14. NON-COMPLIANCE AND ENFORCEMENT

The Company is required to establish adequate enforcement mechanisms and provide for employeesanctions and/or other administrative action, where appropriate, to address any failure by an Investigator to comply with the COI Policy or a Management Plan. Violations of this policy may result in progressive disciplinary action.

An Investigator is non-compliant and in violation of the COI Policy if an Investigator fails to:

1. submit an Annual Disclosure Form or provide an update to the Annual Disclosure Form by the deadlines established for such submissions;
2. provide the CRO with written acknowledgement of a Management Plan; or
3. provide the CRO with requested documentation regarding compliance with a

Management Plan.

If an Investigator fails to comply with the Company's COI Policy or Management Plan, the Company must complete within one-hundred twenty (120) days of determining non-compliance a retrospective review of the Investigator's activities and Research projects, document the Company's determination as to whether the Federally Funded Research or any portion thereof conducted prior to the identification and management of the FCOI was biased in the design, conduct or reporting of such Research.

If bias is found, the Company must submit a mitigation report addressing the impact of the bias on the Research project including the extent of the harm done along with any qualitative and quantitative data to support any actual or future harm, analysis of whether the project is salvageable, and the actions the Company has taken (or will take) to eliminate or mitigate the effect of the bias. Depending on the nature of the FCOI, the Company may determine that additional interim measures are necessary with regards to the Investigator's participation in the Research project between the date the FCOI is identified and the completion of the Company's retrospective review.

15. PROJECT SPECIFIC CERTIFICATION FORM REQUIRED

Each principal investigator or project director involved with a federal funding submission must submit a COI Project Specific Certification Form to the Grants Administration department upon receipt of any Notice of Award on a new or continuing project. The Project Specific Certification Form lists all anticipated Company lab personnel who are responsible for the design, conduct, or reporting of the proposed Research (Investigators) and certifies that such Investigators are compliant with this policy. Information needed to complete the Project Specific Certification Form includes:

- Name of the principal investigator Application deadline
- Funding opportunity announcement number, Funding entity or agency Project title
- Names of personnel, who will design, conduct or report on any of the proposed Research, including but not limited to non-Company Investigators such as collaborators, sub-recipients, contractors or subcontractors proposed to receive funding on the application

The Grants Administration department monitors the status of all grant submissions. Upon receipt of a \$5,000 or more award notice, the Project Specific Certification Form must be completed and submitted in order for the award to be processed.

16. SUBRECIPIENT CONFLICT OF INTEREST COMPLIANCE

If the Company carries out Research through a subrecipient, the Company, as the awardee institution, will take reasonable steps to ensure that any subrecipient Investigator complies with the federal FCOI regulations. The Company will incorporate, as part of a written agreement with the subrecipient, terms that establish whether the FCOI policy of the Company (or that of the

subrecipient) will apply to the subrecipient Investigators.

If the subrecipient's FCOI policy applies to subrecipient Investigators, the subrecipient will certify as part of the agreement that they are in compliance with federal regulations and that their portion of the project is in compliance with their institutional policies on conflict of interest. If the subrecipient cannot provide the certification, the agreement shall state that the subrecipient Investigators are subject to the Company's COI Policy for disclosing SFIs that are directly related to the subrecipient's work for the Company. The Company will, if applicable, submit an FCOI report through the eRA Commons FCOI Module for any FCOIs identified for subrecipient Investigators.

If the subrecipient's COI policy applies to subrecipient Investigators, the agreement shall specify the time period(s) for the subrecipient to report all identified FCOIs to the Company. Such time period(s) must be sufficient to enable the Company to provide timely FCOI reports, as necessary, through the eRA Commons FCOI Module.

If the Company's FCOI policy applies to subrecipient Investigators, the agreement shall specify time periods for the subrecipient to submit all Investigator disclosures of SFIs to the Company. Such time periods should be sufficient to allow the Company to comply with its review, Management, and reporting obligations under the COI Regulations. The Company's Grants Administration department will submit any FCOI reports for subrecipient Investigators through the eRA Commons FCOI Module.

17. ADDITIONAL RESOURCES

NIH/HHS FCOI Policy and Guidance, including the 2011 Revised Regulations and FAQs can be found at: <http://grants.nih.gov/grants/policy/coifaq.htm>.