

FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY

INTRODUCTION

Metselex develops pharmaceuticals. Patients and the public rightly expect our work to be based on sound science, which requires truthful, unbiased design, conduct and reporting of research.

Metselex partners receives government funding to help pay for the research it conducts. When an Investigator receives remuneration from or holds equity interests, for example, in an entity outside of Metselex, such financial interests may give rise to a Financial Conflict of Interest (FCOI) per the Federal regulation cited below. If this is the case, Metselex must have a process in place to identify, manage and report the identified FCOI to the Federal agency (e.g., NIH) when the financial interest (defined as a “significant financial interest”) is determined to be related to the sponsored research and could directly and significantly affect the design, conduct, or reporting of such sponsored research.

The purpose of this policy is to document the requirements and responsibilities associated with identifying and managing Investigator Financial Conflicts of Interest to safeguard the integrity of research by Metselex, Inc. (Company) and to comply with federal regulations [42 CFR Part 50 Subpart F](#), applicable to Public Health Service (PHS) (e.g., National Institutes of Health [NIH]) grants and cooperative agreements, including Phase II SBIR/STTR applications and awards).

Financial conflicts of interest in research involve situations in which an investigator has a significant financial interest that could directly and significantly (have a material effect on the research) affect the design, conduct, or reporting of PHS-funded sponsored research or other federally sponsored research based on Metselex’s broader applicability. Metselex developed this FCOI policy in compliance with HHS regulation [42 CFR Part 50 Subpart F](#) (the Regulation) to ensure that the design, conduct, and reporting of research associated with government sponsored projects is free from bias resulting from an investigator’s conflicting financial interest.

DEFINITIONS

Company means Metselex, Inc.

Financial Conflicts of Interest or **FCOI** in research involve situations in which an investigator has a significant financial interest that may compromise, or have the appearance of compromising, professional judgment in the design, conduct, or reporting of research.

General Counsel means the chief legal representative of the Company.

Investigators include the Principal Investigator and any other individual, regardless of title or position who is responsible for the design, conduct, or reporting of government sponsored research, or proposed for such funding, and which may include for example, collaborators or consultants.

Institutional Responsibilities mean an Investigator's professional responsibilities on behalf of the Company, and as defined by the Company, including but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Manage means taking action to address a Financial Conflict of Interest, which can include reducing or eliminating the Financial Conflict of Interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Principal Investigator or **PI** means the person/people designated as such or the equivalent, e.g., Project Director, in the grant for a Research Project.

Research Project means a project being funded by the Public Health Service (PHS), the National Institutes of Health (NIH) or any other agency or part of the United States government.

Significant Financial Interest or **SFI** is defined below.

Additional definitions are included in the Regulation and can be found at [42 CFR 50.603](#).

REQUIRED FCOI TRAINING

In compliance with federal regulations, all Company Investigators who are planning to participate in or are participating in a Research Project funded by the [National Institutes of Health \(NIH\)](#), the Public Health Service (PHS) and [any other agencies](#) which have chosen to be bound by the PHS FCOI regulation are required to review this Company FCOI policy and complete the [FCOI Training module](#):

- Prior to engaging in research related to any PHS/NIH-funded grant;
- At least every four (4) years;
- Immediately, if:
 - Company revises its FCOI policy in a manner that affects requirements of Investigators
 - An Investigator is new to Company
 - An Investigator is not in compliance with the policy or management plan

Upon completion of the training, a certificate of completion must be sent to the General Counsel. Investigators should also retain a copy for their records.

SIGNIFICANT FINANCIAL INTEREST

A Significant Financial Interest (SFI) is defined as a financial interest consisting of one or more of the following interests of the **Investigator (and those of the Investigator's spouse, registered domestic partner or dependent children)** that reasonably appears to be related to the Investigator's Institutional Responsibilities:

1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received in the past 12 months when aggregated exceeds \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship), as well as equity interest includes any stock, stock option, or other ownership interest, 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 disclosable significant financial interest exists regardless if the value of any financial compensation in the past 12 months when aggregated exceeds \$5,000, or when the Investigator (and those of the Investigator's spouse, registered domestic partner or dependent children) hold any equity interest (e.g., stock, stock options, or other ownership interest), regardless of value.
3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests which when aggregated exceeds \$5,000.
4. Investigators must disclose any reimbursed or sponsored travel (sponsored travel is 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, which when aggregated per reimbursing entity exceeds \$5,000, provided:
 - a. This disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency in the United States, or a public or non-profit institution of higher education (as defined at 20 U.S.C. 1001(a)) in the United States or its affiliated hospital, medical center or research institute in the United States.
 - b. For example, if the PI travels to a scientific seminar but does not pay or receive reimbursement by the Company directly (i.e. the travel was paid for by a third party/sponsor), the PI is required to disclose basic information to the Company relating to the trip, such as purpose of the trip, identity of the payer/sponsor, destination and duration. Such travel payments may be considered compensation from a third party, so Company is required to determine if additional information is required (e.g. monetary value) and whether the travel constitutes an SFI with PHS/NIH-funded research.

5. All foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

The term Significant Financial Interest **does not include** the following types of financial interests:

1. Salary, royalties, or other remuneration paid by Company to the Investigator if the Investigator is currently employed or otherwise appointed by the Company, including intellectual property rights assigned to the Company and agreements to share in royalties related to such rights.
2. Any ownership interest in the Company held by the Investigator.
3. 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.
4. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency in the United States, a public or non-profit institution of higher education (as defined at 20 U.S.C. 1001(a)) in the United States or its affiliated hospital, medical center, or research institute in the United States.
5. Income from service on advisory committees or review panels for a Federal, state, or local government agency in the United States, or a United States institution of higher education.

IDENTIFICATION OF PERSONS REQUIRED TO DISCLOSE AN SFI

The Principal Investigator of a Research Project will identify all Investigators who must complete a significant financial interest disclosure. The Principal Investigator and General Counsel will be responsible for ensuring that annual updates are completed. Investigator is responsible for submitting a new or updated disclosure form within 30 days if the Investigator (i) has acquired a new Significant Financial Interest, e.g., by marriage or inheritance; or (ii) the value of a previously excluded financial interest has increased in value such that it is now longer excluded, e.g., if the value has crossed the \$5,000 threshold for several exclusions.

SUBMISSION OF SIGNIFICANT FINANCIAL INTEREST DISCLOSURE FORM

Each Investigator identified by the PI will be required to complete the SFI Disclosure Form and submit it to the General Counsel:

- Before applying for and promptly when a sponsoring agency begins discussions with the Company about funding prior to expenditure of any PHS/NIH funds on a Research Project,
- By January 31st of each year, during the period of the funding award, and

- Within 30 days of discovering or acquiring a new SFI, including due to marriage, purchase, gift, inheritance or otherwise.

REVIEW OF FINANCIAL INTEREST DISCLOSURE FORM:

A review of each submitted SFI Disclosure Form will be conducted by the General Counsel with input from the relevant Investigator to determine whether a financial conflict of interest exists. The requirement that an Investigator discloses a Significant Financial Interest under the terms of this Policy does not in and of itself imply the existence of an actual Financial Conflict of Interest.

A Financial Conflict of Interest exists when Investigator's Significant Financial Interest:

- Is related to a Research Project, that is, the SFI could be affected by the Research Project or is in an entity whose financial interests could be affected by the Research Project; and
- When the SFI could directly and significantly (could have a material affect on the research) affect the design, conduct, or reporting of the Research Project.

If it is determined that there is a financial conflict of interest, then steps will be taken to determine what measures are needed to manage, reduce or eliminate the FCOI to prevent bias in the research and promote objectivity regarding the design, conduct or reporting of the Research Project.

When an FCOI is identified, a management plan will be required to outline the terms, conditions, and restrictions, if any, to manage the FCOI. The management plan may require one or more of the following actions (but not limited to) to be taken:

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research, to staff members working on the project, to the Institution Review Board(s), to the Institutional Animal Care and Use Committee(s), etc.).
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants.
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the Research Project against bias resulting from the Financial Conflict of Interest.
- Modification of the Research Project plan.
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the Research Project.
- Reduction or elimination of the financial interest (e.g., sale of an equity interest).
- Severance of relationships that create financial conflicts.

REPORTING REQUIREMENTS

The General Counsel is responsible for reporting identified FCOIs to the awarding components in accordance with applicable federal requirements. The following reports are required by the sponsor:

1. Initial report

Prior to the Company's expenditure of any award funds under a Research Project, the Company will provide to the sponsoring agency an FCOI report regarding any Investigator SFI found by the Company to be a Financial Conflict of Interest in accordance with the regulation. In cases in which the Company identifies an FCOI and eliminates it prior to the expenditure of awarded funds, the Company shall not submit an FCOI report.

2. During on-going Research Projects

Whenever, during the Research Project, a new Investigator discloses a Significant Financial Interest or an existing Investigator discloses a new Significant Financial Interest which the Company determines to be a Financial Conflict of Interest, the Company will submit an FCOI report within 60 days after its determination that a new FCOI exists.

Whenever Company identifies an SFI that was not disclosed timely by an Investigator or not previously reviewed by the Company during the period of an on-going Research Project, the Company will within 60 days:

- Review the SFI; determine whether it is related to the Research Project and whether a FCOI exists. If so, the Company will
 - Submit a FCOI report.
 - 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 going forward.
- 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 Company to constitute a FCOI;
 - Failure by the Company to review or manage such a FCOI; or
 - Failure by the Investigator to comply with a FCOI management plan;

The Company will complete a retrospective review within 120 days of discovery of noncompliance to determine whether any Research Project, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such Research Project. Updated FCOI reports will be submitted to the sponsor if new information is found following completion of the retrospective review. Required retrospective review documentation requirements are outlined in 42 CFR 50.605(a)(3)(iii) and should at minimum include:

- Project Number

- Project Title
- PD/PI or contact PD/PI if multiple PD/PI model is used
- Name of the Investigator with the FCOI
- Name of the entity with which the Investigator has an FCOI
- Reasons for the retrospective review
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed)
- Findings of the review
- Conclusions of the review

3. Annual FCOI report

For any FCOI previously reported to the sponsor, the Company shall provide an annual FCOI report addressing the status of the FCOI (i.e., is the FCOI being managed or does it no longer exist). If the management plan is being managed, the Company will provide any changes to the management plan, if applicable, at the same time that the Company is required to submit to NIH the annual progress report, multi-year progress report, if applicable, or at time of extension.

4. Problem report

At any time, Company will notify the sponsor promptly if:

- **Bias is found.** Company will notify and submit a mitigation report to the sponsor if bias is found following the completion of a retrospective review. The mitigation report will include, at a minimum, the key elements documented in the retrospective review (discussed above) and a description of the impact of the bias on the Research Project and the Company'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, the Company will submit FCOI reports annually.
- **An Investigator fails to comply.** If an Investigator fails to comply with the Company's FCOI policy or if an FCOI management plan appears to have biased the design, conduct, or reporting of the Research Project, Company will promptly notify the sponsor and take corrective further action as described in [42 CFR 50.606\(a\)](#).

MANAGEMENT PLAN

If an Investigator is found to have a Financial Conflict of Interest upon the issuance of a new award, a management plan is to be implemented prior to Company's expenditure of government funds awarded for the Research Project. The FCOI report to the sponsor will specify the actions that are required to manage the FCOI, and will include a description of at least the key elements outlined below:

- The role and principal duties of the conflicted Investigator in the Research Project
- Conditions of the management plan
- How the management plan is designed to safeguard objectivity in the Research Project
- Confirmation of the Investigator's agreement to the management plan
- How the management plan will be monitored to ensure Investigator compliance
- Other information as needed

Investigators must formally agree to the proposed management plan. All management plans are required to be signed by the relevant Investigator, the PI and the CEO of Company. Compliance of the management plan will be monitored by the Principal Investigator and the General Counsel on behalf of the Company. Additional management plan requirements are outlined below

VIOLATIONS OF FCOI POLICY

Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of significant financial interest or failure to comply with a requirement of the management plan, disciplinary proceedings may be taken against the violating individual.

Company will follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy as described above. The sponsoring agency may take its own action as it deems appropriate, including the suspension of the funding for the Investigator until the matter is resolved.

Additionally, in any case in which the purpose of a Research Project is clinical research to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported by Company as required by this policy, Company will require the Investigator involved to disclose the Financial Conflict of Interest in each public presentation of the results of the Research Project and to request an addendum to previously published presentations.

MAINTENANCE OF RECORDS

Records of Investigator SFI Disclosure forms and of actions taken to manage actual or potential Financial Conflicts of Interest shall be retained by Company for three (3) years from the date the final expenditure report is submitted to the sponsor or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

SUBRECIPIENT REQUIREMENTS

When carrying out the Research Project through a subrecipient (e.g., a university, foundation or corporation), Company will determine whether to rely on this Company FCOI policy or the subrecipient's FCOI policy. If relying on the subrecipient's FCOI's policy, Company shall establish a written agreement which confirms that the Investigators of the subrecipient will comply with this policy or provide certification that the subrecipient legal entity complies with the Federal policy, 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F). Specifically, Company must enter into a formal written agreement with each subrecipient or consortium participant that addresses the negotiated arrangements for meeting the scientific, administrative, financial, and reporting requirements of the grant, including those necessary to ensure compliance with all applicable Federal regulations and policies and facilitate an efficient collaborative venture. At a minimum, this agreement must include the following:

- Terms that establish whether Company's Financial Conflict of Interest policy or that of the subrecipient will apply to the subrecipient's Investigators.
- If the subrecipient's Investigators must comply with the subrecipient's Financial Conflict of Interest policy, the subrecipient shall certify as part of the written agreement that its policy complies with the 2011 revised FCOI regulation (42 CFR Part 50 Subpart F). If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to Company's Financial Conflict of Interest policy for disclosing Significant Financial Interests that are directly related to the subrecipient's work for Company.
- If the subrecipient's Investigators must comply with the subrecipient's Financial Conflict of Interest policy, the written agreement shall specify time period(s) for the subrecipient to report all identified Financial Conflicts of Interest to Company. Such time period(s) shall be sufficient to enable Company to provide timely FCOI reports, as necessary, to the sponsor as required by the regulation.
- Alternatively, if the subrecipient's Investigators must comply with Company's Financial Conflict of Interest policy, the written agreement shall specify time period(s) for the subrecipient to submit all Investigator disclosures of Significant Financial Interests to Company. Such time period(s) shall be sufficient to enable Company to comply timely with its review, management, and reporting obligations under the 2011 revised FCOI regulation.

PUBLIC DISCLOSURE AND RECORDS MANAGEMENT

Company will publish this policy on its public website. Company will also maintain public accessibility to Significant Financial Interests of senior/key personnel that were identified as having FCOIs. Senior/key personnel means the Project Director/Principal Investigator (PD/PI)

and any other person identified as senior/key personnel in the grant application, progress report, or any other report submitted to the sponsor by Company.

Company will respond to all written requests for information within five business days and then release the following information about each such Significant Financial Interest.

- The name of the Investigator.
- The title and role of the Investigator with respect to the research project.
- Name of the entity with which the Significant Financial Interest is held.
- The nature of the Significant Financial Interest.
- Approximate value of the Significant Financial Interest as determined by:
 - dollar range \$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 a value cannot be readily determined through reference to public prices or reasonable measures of fair market value.

Upon request from the sponsor, Company will also make available information relating to any Investigator SFI disclosure and the institutional review available, whether or not the disclosure resulted in the institution's determination of an FCOI.

FCOI IN RESEARCH INVOLVING HUMAN SUBJECTS

Additional consideration will be given to Financial Conflicts of Interest when a Research Project involves human participants. In addition to the process outlined above, any significant financial conflict identified will be disclosed to the Institutional Review Board (IRB) responsible for review and approval of the associated protocols. The Research Project will not begin/resume until the IRB has confirmed that appropriate steps have been taken to ameliorate any potential harm or potential harm to participants due to the significant financial conflict.

USEFUL RESOURCES

[FCOI Regulation 42 CFR Part 50 Subpart F](#)

[NIH Financial Conflict of Interest](#)

[FCOI Training](#)

[Frequently Asked Questions \(FAQs\)](#)

[NIH Guide Notices Related to Financial Conflict of Interest](#)

[Subscribe to Weekly TOC E-Mail with New NIH Guide Postings and Funding Opportunities](#)

[Important Highlights of FCOI Regulatory Requirements for Foreign Institutions](#)

Significant Financial Interest (SFI) Disclosure Form

Capitalized terms in this form are defined in the Metselex Financial Conflict of Interest Policy. For convenience, the definition of Significant Financial Disclosure is included at the end of this form.

This form is to be completed by each Metselex employee who has been identified by a Principal Investigator or Principal Director of a government funded Metselex Research Project as someone who is or plans to be an Investigator for the Research Project. This form must be completed by all Investigators on each Research Project, even if the Investigator has no relevant Significant Financial Interests (to confirm the lack of such an interest).

A new or updated version of this form must be completed for each Research Project:

- Before applying for and prior to expenditure of any PHS/NIH funds on a Research Project,
- By January 31st of each year, during the period of the funding award, and
- Within 30 days of discovering or acquiring a new SFI, including due to marriage, purchase, gift, inheritance or otherwise.

The form must be completed with information relating to **Investigator (and the Investigator's spouse, registered domestic partner or dependent children)** that reasonably appears to be related to the Investigator's Institutional Responsibilities.

Once completed, the form should be submitted to Metselex' General Counsel.

Investigator and Research Project Identification

This submittal is a ___ New Disclosure ___ Updated Disclosure

Disclosing Investigator Name:

Disclosing Investigator Email:

Research Project Title:

Research Project Agency:

Research Project Agency Award Number (if known):

Entity Disclosure

Include all Significant Financial Interests (see definition at the end of this form).

Entity Name	Disclosure Type (Check all that apply)	Do these interest relate to the above-identified Research Project?
Name: <input type="checkbox"/> Publicly traded <input type="checkbox"/> Non-publicly traded <input type="checkbox"/> Foreign entity Did you acquire the interest in the past 30 days? <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Income: <input type="checkbox"/> IP (royalties, license fees, etc.) <input type="checkbox"/> Stock and/or stock options Number of shares: Estimated Stock Value*: % of issued and outstanding shares: * If a value cannot be readily determined through reference to public prices or reasonable measures of fair market value, enter N/A.	<input type="checkbox"/> Yes <input type="checkbox"/> No Explanation (required for both Yes and No):
Name: <input type="checkbox"/> Publicly traded <input type="checkbox"/> Non-publicly traded <input type="checkbox"/> Foreign entity Did you acquire the interest in the past 30 days? <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Income: <input type="checkbox"/> IP (royalties, license fees, etc.) <input type="checkbox"/> Stock and/or stock options Number of shares: Estimated Stock Value*: % of issued and outstanding shares: * If a value cannot be readily determined through reference to public prices or reasonable measures of fair market value, enter N/A.	<input type="checkbox"/> Yes <input type="checkbox"/> No Explanation (required for both Yes and No):
Name: <input type="checkbox"/> Publicly traded <input type="checkbox"/> Non-publicly traded <input type="checkbox"/> Foreign entity Did you acquire the interest in the past 30 days? <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Income: <input type="checkbox"/> IP (royalties, license fees, etc.) <input type="checkbox"/> Stock and/or stock options Number of shares: Estimated Stock Value*: % of issued and outstanding shares: * If a value cannot be readily determined through reference to public prices or reasonable measures of fair market value, enter N/A.	<input type="checkbox"/> Yes <input type="checkbox"/> No Explanation (required for both Yes and No):

If you need to provide information about more entities, duplicate this page.

Reimbursed or Sponsored Travel Disclosure

Report all travel in excess of \$5,000 per entity. Exclude travel that is reimbursed or sponsored by a U.S. federal, state, or local government agency in the United States, an institution of higher education as defined by 20 U.S.C. 1001(a) in the United States, an academic teaching hospital, a medical center, or a research institute in the United States affiliated with an institution of higher education in the United States.

Recent Travel (last 12 months in excess of \$5,000 per entity)

Entity	Destination	Duration	Purpose of trip

Planned Travel (upcoming 12 months)

Entity	Destination	Duration	Purpose of trip

If you need to provide information about more travel, duplicate this page.

Entity Details

Complete this section for **each Entity** listed in the disclosure sections above.

Name of Entity:

Entity's address:

Principal business of Entity:

1. If you received any consulting income from the Entity, please specifically describe the nature of your consulting activities or services.
2. If you received other income or payment for services from the Entity, please describe the services for which payment was received.
3. Does the Research project involve testing of any drugs or medical devices or the development of a product or service of interest to the Entity?
 No Yes – if yes, please explain:
4. Does or will the Entity manufacture or commercialize any device, procedure, drug, vaccine or any other product that is associated with or that will predictably result from the Research Project?
 No Yes – if yes, please explain:
5. Is it reasonable to anticipate that the Entity could be affected by the Research Project? Affect may include, but is not limited to, business impact of a licensing interest in research results.
 No Yes – for either answer, please explain:
6. If you, your spouse, registered domestic partner and/or dependent children hold a position of management with the Entity, state the position title, describe the responsibilities of the position, and explain and relationship to the Research Project.

7. If the Research Project includes the Entity as a sub-awardee, subcontractor, consortium member, supplier of goods or services, lessor or other involvement in the Research Project, or if the Entity will provide proprietary data, test materials, equipment, facilities, personnel or the like for use in the Research Project, explain and describe.

8. How will you keep your interests and obligations to the Entity separate from your Metselex activities associated with the Research Project? Responses could include examples of a clear division of the Entity's goals and business interests and the aims of the Research Project.

9. Does the Entity hold any intellectual property rights which will be used in the Research Project? Describe any intellectual property rights for which you, your spouse, registered domestic partner and/or dependent children are receiving license fees, royalties or other payments.

If you have multiple Entities, duplicate this section.

Certification by Disclosing Investigator

I, the above named Investigator, certify under penalty of perjury that this is a complete disclosure of my Significant Financial Interests related to my Institutional Responsibilities, that I have used all reasonable diligence in preparing this Financial Conflict of Interest Disclosure, and to the best of my knowledge it is true and complete. I also acknowledge that by signing my name below that it is my responsibility to disclose to Metselex, within 30 days, any new Significant Financial Interest obtained during the term of the Research Project.

Signature:

Date:

Notice: The information provided herein may be released or transmitted to the sponsoring agency for the Research Project, including Federal agency representatives. This record will be retained for at least 3 years after termination of the Research Project or until resolution of any action by the sponsor relating to the Research Project, whichever is greater. This records will be retained by the General Counsel of Metselex.

SIGNIFICANT FINANCIAL INTEREST DEFINITION

A Significant Financial Interest (SFI) is defined as a financial interest consisting of one or more of the following interests of the **Investigator (and those of the Investigator's spouse, registered domestic partner or dependent children)** that reasonably appears to be related to the Investigator's Institutional Responsibilities:

1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received in the past 12 months when aggregated exceeds \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship), as well as equity interest includes any stock, stock option, or other ownership interest, 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 disclosable significant financial interest exists regardless if the value of any financial compensation in the past 12 months when aggregated exceeds \$5,000, or when the Investigator (and those of the Investigator's spouse, registered domestic partner or dependent children) hold any equity interest (e.g., stock, stock options, or other ownership interest), regardless of value.
3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests which when aggregated exceeds \$5,000.
4. Investigators must disclose any reimbursed or sponsored travel (sponsored travel is 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, which when aggregated per reimbursing entity exceeds \$5,000, provided:
 - a. This disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency in the United States, or a public or non-profit institution of higher education (as defined at 20 U.S.C. 1001(a)) in the United States or its affiliated hospital, medical center or research institute in the United States.
 - b. For example, if the PI travels to a scientific seminar but does not pay or receive reimbursement by the Company directly (i.e. the travel was paid for by a third party/sponsor), the PI is required to disclose basic information to the Company relating to the trip, such as purpose of the trip, identity of the payer/sponsor, destination and duration. Such travel payments may be considered compensation from a third party, so Company is required to determine if additional information is required (e.g. monetary value) and whether the travel constitutes an SFI with PHS/NIH-funded research.
5. All foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or a foreign government (which includes local, provincial, or equivalent

governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

The term Significant Financial Interest **does not include** the following types of financial interests:

1. Salary, royalties, or other remuneration paid by Company to the Investigator if the Investigator is currently employed or otherwise appointed by the Company, including intellectual property rights assigned to the Company and agreements to share in royalties related to such rights.
2. Any ownership interest in the Company held by the Investigator.
3. 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.
4. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency in the United States, a public or non-profit institution of higher education (as defined at 20 U.S.C. 1001(a)) in the United States or its affiliated hospital, medical center, or research institute in the United States.
5. Income from service on advisory committees or review panels for a Federal, state, or local government agency in the United States, or a United States institution of higher education.