

RELIANT MEDICAL GROUP, INC.	ADMINISTRATIVE POLICY MANUAL
SUBJECT: Financial Conflicts of Interest in PHS-Funded Research	RESEARCH

Financial Conflicts of Interest in PHS-Funded Research

Policy

It is the policy of Reliant Medical Group, Inc. (“Reliant”) to ensure that the conduct and reporting of research will not be inappropriately influenced by any financial interest or leadership role of Reliant researchers or research staff.

Purpose

The purpose of this policy is to ensure the highest level of integrity in the conduct of PHS-funded clinical and scientific research at Reliant.

Scope

This policy applies to Investigators of PHS-funded research projects conducted at Reliant or in which Reliant participates.

Definitions

Designated Official (DO): The Designated Official for all Medical Groups will be the Reliant Medical Director of Research.

Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable.

Financial Conflict of Interest (FCOI): A Significant Financial Interest or Travel that could directly and significantly affect the design, conduct, or reporting of Research.

Institutional Responsibilities: An Investigator’s professional responsibilities on behalf of Reliant. These may include, for example, activities such as clinical care, research, research consultation, teaching, and professional practice; and other activities, such as serving on a Reliant committee or board.

Investigator: The project director (PD) or principal investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, which may include, for example, collaborators or consultants.

Leadership Role: A leadership role includes employment, consulting in any administrative or executive capacity, or serving as (i) a member of a board of trustees or board of directors, (ii) an

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officer, or (iii) a member of an advisory committee, advisory board, or subcommittee of a board of trustees or of a board of directors, whether remunerated or non-remunerated.

Public Health Service (PHS): The Public Health Service includes various agencies that fund research. The PHS, through its funding agencies, enforces the Department of Health and Human Services' (DHHS) Rule entitled "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors" and codified at 42 C.F.R. Parts 50 and 94. The various agencies under PHS jurisdiction includes: National Institutes of Health (NIH); Centers for Disease Control and Prevention (CDC); Food and Drug Administration (FDA); Indian Health Service (HIS); Office of Assistant Secretary for Preparedness and Response (ASPR); Health Resources and Services Administration (HRSA); Office of Global Affairs (OGA); Agency for Toxic Substances and Disease Registry (ATSDR); Agency for Healthcare Research and Quality (AHRQ); Office of the Assistant Secretary for Health (OASH); and Substance Abuse & Mental Health Services Administration (SAMHSA).

Reviewable Interest: Any Significant Financial Interest (SFI) and/or Leadership Role belonging to an Investigator or an Investigator's Family, and Travel.

Senior/Key Personnel: The project director (PD) or principal investigator (PI) and any other person identified in the grant application, progress report, or any other report submitted to the Public Health Service as senior/key personnel under the auspices of a Medical Group .

Significant Financial Interest (SFI): A financial interest consisting of one or more of the following interests:

1. With regard to any **publicly traded entity**, when the value of any **remuneration** (salary and any payment for services not otherwise identified as salary, for example consulting fees, honoraria, paid authorship) received from the entity in the twelve (12) months preceding disclosure of the interest **aggregated with** the value of any **equity** in the entity (for example, stock, stock options, or other ownership interests as determined through reference to public prices or other reasonable measures of fair market value) in the entity as of the date of the disclosure **exceeds \$5,000**;
2. With regard to any **non-publicly traded entity**, when the aggregated value of any **remuneration** received from the entity in the twelve (12) months preceding disclosure of the interest **exceeds \$5,000** or any **equity** in the entity; or

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

Exclusions: The term Significant Financial Interest does **not include** the following types of financial interests: salary, royalties, or other remuneration paid by Reliant to an Investigator if the Investigator is currently employed by or contracted to Reliant, including intellectual property rights assigned to Reliant and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, 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.

Travel: Any travel that is reimbursed (i.e., the Investigator is made whole for the financial outlay required) or sponsored (i.e., the costs are paid on behalf of the Investigator such that the exact monetary value may not be readily available) other than 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.

Requirements

This policy is intended to comply with the requirements set forth in the United States Department of Health and Human Services Final Rule, Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors, (August 25, 2011) (42 CFR 50.601 et seq. and 45 CFR 94.1 et seq.).

In addition to complying with the requirements of this policy, Reliant Investigators remain subject to any and all requirements (i) imposed by the reviewing Institutional Review Board (IRB), a Medical Group's Research Conflicts of Interest Committee or other conflicts oversight body, and/or (ii) contained within other applicable Reliant policies and procedures, including parallel obligations to disclose financial and other information required by those policies and procedures.

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Procedure

A. Disclosure by Investigators to Reliant

Each Investigator must complete the Disclosure Statement Form and return it to the Department of Clinical Research (“Research Department”) with the research project proposal, prior to any application for funding, and annually until the Investigator’s active involvement in the study, including data analysis ends or the period of award ends, whichever is later. See Attachment A.

Any new Reviewable Interest that is discovered or acquired during the course of a PHS-funded research project must be reported to Research Department within 30 days after it is discovered or acquired.

Certain responses may require an Investigator to complete the Outside Activities Reporting Form. See Attachment B.

Investigators must provide in a timely manner any additional information requested by Reliant regarding information disclosed on the Disclosure Statement Form or Outside Activities Reporting Form.

It is the responsibility of the Principal Investigator to ensure that each Investigator working under his/her supervision on a research project submits the Disclosure Statement Form as required by this policy.

Investigators are reminded that the evaluation of interests and management of any identified Financial Conflicts of Interest (FCOI), as further described in the subsequent sections, must be completed in accordance with this policy prior to the expenditure of any funding.

B. Review of Disclosures and Relatedness Determination

The Designated Official or designee (DO) will review any disclosed Reviewable Interest to determine whether it related to the Investigator’s proposed research. A Reviewable Interest will be found to relate to the Investigator’s research when it is reasonably determined that the Reviewable Interest could be affected by the research, or is in an entity whose financial interest could be affected by the research. The Investigator may be asked to provide information to assist in the assessment of whether a Reviewable Interest is related to the Investigator’s research and shall do so in a timely manner. The DO will communicate with

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the Investigator’s supervisor and Chief Medical Officer (CMO) regarding disclosures made by its Investigators.

C. Determination of Conflicts of Interest

The DO will evaluate each Reviewable Interest that is found to relate to an Investigator’s research to make a reasonable determination whether a Conflict of Interest (FCOI) exists.

A FCOI will be found to exist when a Reviewable Interest related to the Investigator’s research could directly and significantly affect the design, conduct, or reporting of the research.

The DO will initiate any factual inquiries necessary to determine whether a FCOI exists, including seeking additional information from the Investigator responsible for the research project as appropriate, and may then render a decision regarding the related Reviewable Interest pursuant to criteria established by Reliant. In difficult or ambiguous cases, the DO will consult with the CMO and may also refer the question of whether an FCOI exists to Reliant’s Conflict of Interest Review Committee (“CIRC”). The composition of the CIRC shall consist, at a minimum, of the DO (CIRC Chair), the Compliance Officer, the CMO. The DO shall take every precaution to assure the objectivity and confidentiality of the proceedings.

D. Management of Identified Financial Conflicts of Interest

The DO shall be principally responsible for determining the appropriate response to manage an identified FCOI. Responses may include: (1) finding that the research may not proceed because of the conflict, in which case the conflict must be eliminated through divestiture of the financial interest, severance of the business relationship causing the conflict, or other action, before the research may be able to proceed; or (2) finding that the research may proceed if the conflict is managed in accordance with the plan developed by the DO in consultation with the Investigator’s supervisor and the CMO.

In the event that the DO determines that a more formal review of a management plan is appropriate, the CIRC may be involved in the management plan development. In cases where an FCOI has been identified and must be eliminated or managed, and where resolution is difficult, the CIRC may seek to review its recommended management plan with the Chair of the Board of Trustees (the “Board”), who may initiate a review by a committee or subcommittee of the Board, at the Chair’s discretion, for input and resolution.

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Research in which an Investigator is found to have an FCOI will not be permitted to proceed until the Investigator has agreed to implement the written management plan presented by the DO, alone or in conjunction with the CIRC.

Methods of managing FCOIs that the DO and/or the CIRC may impose, solely or in combination with one another, include but are not limited to:

- Referring the research project to non-conflicted Investigators at Reliant, thus removing the conflicted Investigator from participation;
- Requiring that certain aspects of the research (e.g., subject consent/enrollment, data analysis, publication, etc.) are performed by a non-conflicted member of the research team and limiting the conflicted member to non-critical tasks;
- Modification of the research plan;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest or requiring that problematic investments related to a research study be “frozen” for a designated period of time lasting beyond the termination of the study, with the Investigator allowed neither to sell nor transfer those interests until the end of the designated time period);
- Severance of relationships that create the FCOI. Public disclosure of the FCOI (e.g., disclosing the conflict of interest to sponsors and/or journals and other publications, as well as when presenting the research);
- For research involving human subjects, disclosure of the FCOI directly to participants;
- Requiring independent monitoring and oversight of interactions between subjects and the research team, data gathering, data analysis, and/or data reporting by an individual who is capable of taking measures to protect against bias in the design, conduct and reporting of the research;
- Arranging for heightened review of all adverse events, including review of subject records on a comprehensive, periodic or sampled basis to assure that reports of adverse events have been timely and properly made; and/or
- Requiring more frequent than annual updating to the DO and/or the CIRC of information related to the FCOI, if it appears that the FCOI might change in any appreciable way over the course of the research project.

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Reliant reserves the right to impose any requirements it sees fit on any disclosed interests and roles, even those that do not constitute Reviewable Interests and/or do not constitute an FCOI requiring management in accordance with this policy and/or applicable regulations; this may be done in order to achieve transparency, ensure accountability, or address other issues relating to those interests and roles. Reliant may develop additional procedures and/or guidance regarding these types of interests and roles and any associated limitations or requirements.

In any case in which the DHHS 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 an FCOI that was not managed or reported by Reliant, the Investigator will be required to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

Investigators have an on-going obligation to adhere to an imposed management plan and failure to do so may be grounds for sanctions under this policy.

E. New Interests That Arise During an On-Going Research Project

To the extent a new Reviewable Interest is disclosed to Reliant in the course of an on-going research project (i.e., an Investigator who is new to participating in the research discloses a Reviewable Interest or an existing Investigator discloses a new Reviewable Interest), or Reliant identifies a Reviewable Interest that was not previously reviewed in a timely manner in accordance with this policy (e.g., was not timely reviewed or reported by a sub recipient), the DO or designee will, within a reasonable period of time that for PHS-funded research not to exceed sixty (60) days from the date of the disclosure: (i) determine if the Reviewable Interest relates to the Investigator’s research; (ii) if it relates, determine if it qualifies as an FCOI; and (iii) if it is an FCOI, implement on at least an interim basis a management plan in accordance with this policy. The DO may, depending on the circumstances of the Reviewable Interest, conclude that additional interim measures are necessary with regard to the Investigator’s participation in the research between the date of disclosure or identification and the completion of the Director’s review (including, where warranted, a retrospective review as discussed below).

F. Retrospective Reviews; Mitigation Reports

Retrospective Review for Bias

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There may be times when an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose a Reviewable Interest that is determined to constitute an FCOI; failure by Reliant to review or manage such an FCOI; or failure by the Investigator to comply with an FCOI management plan. In the event such noncompliance is identified, Reliant will, within 120 days of determining noncompliance, complete a retrospective review of the Investigator's activities and the research to determine whether any research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct or reporting of such research. Any FCOI report submitted to the PHS awarding agency with respect to such research will be updated as necessary in light of the results of the retrospective review.

Documentation of Retrospective Review

Reliant will document at least the following information regarding any retrospective review:

1. Project number. Project title.
2. Project director (PD)/principal investigator (PI) or contact PD/PI if a multiple
3. PD/PI model is used.
4. Name of the Investigator with the FCOI.
5. Name of the entity with which the Investigator has a FCOI.
6. Reason(s) for the retrospective review.
7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed). Findings of the review.
8. Conclusions of the review.

Notification of Awarding Agency; Mitigation Report

If bias is found in the design, conduct or reporting of the research during the period of noncompliance, Reliant will promptly notify the relevant PHS awarding agency and will submit a mitigation report, which will include at least the elements documented in the retrospective review (see above) and a description of the impact of the bias on the research project and Reliant's plan of action or actions taken to eliminate or mitigate the effect of the bias.

G. Notification and Reporting

PHS Awarding Agency

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For PHS-funded research, Reliant will provide all required notifications and reports to the relevant PHS awarding agency, in accordance with applicable regulations, this policy and required timeframes. To the extent Reliant is receiving PHS funding through a subaward (but nonetheless applying the terms of this policy), any required reports will be made in the manner specified by the terms of the relevant subaward agreement.

1. FCOI Reports

If required, Reliant will report identified FCOIs that are related to PHS-funded research to the relevant PHS awarding agency, whether identified in advance of commencing a PHS-funded research project (an “Initial FCOI Report”) or in the course of an on-going PHS-funded research project as a result of new or newly identified FCOI information (“Updated FCOI Report”). For any identified FCOI related to on-going PHS-funded research that was previously reported in an Initial FCOI Report, Reliant will provide the PHS awarding agency with an annual FCOI report that addresses the status of the FCOI (including any changes in the value of the previously reported interest) and any changes to the management plan (“Annual FCOI Report”), or explain why the FCOI no longer exists. Such Annual FCOI Reports will be provided for the duration of the PHS-funded research.

2. Timing of FCOI Reports

Reliant will provide required FCOI reports in accordance with the following timeframes:

- a. Initial FCOI Reports: prior to the expenditure of funds.
- b. Updated FCOI Reports: within sixty (60) days of identification of a new FCOI pursuant to this policy (whether due to a new Investigator or a new FCOI disclosed by an existing Investigator) or identification of an FCOI that was not timely disclosed or managed.
- c. Annual FCOI Reports: at least annually, in accordance with the awarding agency’s specifications. The Annual FCOI Report is due at the same time as Reliant is required to submit the annual progress report for a grant, including a multi-year funded progress report if applicable, or at the time of the extension.

3. Content of FCOI Reports

Any FCOI Report made to the PHS awarding agency shall provide sufficient information to enable the agency to understand the nature and extent of the FCOI and to assess the

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appropriateness of Reliant’s management plan. Any FCOI Report will include at least the following information:

- a. Project number.
- b. PD/PI or contact PD/PI if a multiple PD/PI model is used
- c. Name of the Investigator with the FCOI.
- d. Name of the entity with which the Investigator has a FCOI.
- e. Nature of the interest that forms the basis of the FCOI (e.g., equity, consulting fee, travel reimbursement, honorarium).
- f. Value of the interest provided in dollar ranges, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
- g. A description of how the interest relates to the PHS-funded research and the basis for Reliant’s determination that the interest conflicts with such research.
- h. A description of the key elements of the management plan, including:
 - i. The role and principal duties of the conflicted Investigator in the research.
 - ii. The conditions of the management plan.
 - iii. How the management plan is designed to safeguard objectivity in the research.
 - iv. Confirmation of the Investigator’s agreement to the management plan.
 - v. How the management plan will be monitored to ensure Investigator compliance.
 - vi. Any other information deemed necessary to meet Reliant’s obligations under applicable regulations and this policy.

Additional Notifications

In addition to the required FCOI reports, Reliant will promptly notify the relevant PHS awarding agency in the event that it finds that an Investigator’s failure to comply with this policy or an imposed management plan has biased the design, conduct, or reporting of PHS-funded research (such notification will include the corrective action taken or to be taken in response to the identified Investigator non-compliance).

The DO shall provide the Board with an annual report summarizing all of the identified conflicts and resolutions for the preceding year.

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H. Requirements for Subrecipients of PHS-Funded Research

Reliant may from time to time carry out aspects of PHS-funded research through a subrecipient with which it contracts through a subaward agreement or other similar contract to provide research funding; alternatively, Reliant may receive PHS funding as a subrecipient through a subaward agreement with the prime institution. When proposed PHS-funded research is to be carried out through a subrecipient (i.e., Reliant is the prime awardee carrying out the research through a subrecipient), Reliant will establish in writing whether this policy, or that of the subrecipient will apply to the subrecipient’s Investigators, as well as the time frames within which the subrecipient must provide any information necessary to ensure that Reliant is able to meet its reporting obligations to the PHS awarding agency. When Reliant receives PHS funds through a subaward agreement, the application of this policy to that research will be subject to the terms of any applicable agreement with the prime awardee.

I. Public Access

For PHS-funded research, Reliant will ensure public accessibility of information concerning the FCOIs currently held by Senior/Key Personnel subject to this policy. Unless and until Reliant establishes a mechanism of making such information available through a publicly accessible website, Reliant will provide a written response within five (5) business days of receipt by the DO of a complete written request for information regarding any SFI disclosed and still held by a Senior/Key Personnel subject to this policy that has been determined to relate to the PHS-funded research and constitute an FCOI pursuant to this policy. Individuals seeking to make such requests should mail them to the attention of the Director of Research for Reliant at 630 Plantation Street, Worcester MA 01605

J. Leadership Roles

In addition to financial interests, an Investigator’s Leadership Roles, even where unpaid, in entities that have a stake in the outcome of the research (for example, an entity that manufactures the technology being investigated) will be evaluated by the DO, with the assistance of the CIRC where appropriate, to determine whether a Leadership Role is related to an Investigator’s proposed research and raises any concerns that must be addressed prior to the commencement of the research.

K. Training

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Investigators must complete all conflicts of interest training required by a relevant PHS awarding agency prior to engaging in research at or under the auspices of Reliant and at least every four years following the initial training. Additionally, Investigators will be required to receive training immediately, which would be as soon as reasonably practical after learning of any of the following circumstances:

- Reliant revises this policy or accompanying procedures in any manner that affects the requirements applicable to Investigators;
- Anyone newly employed as an Investigator Reliant at Reliant;
- Any newly engaged Investigator to which this policy has been deemed applicable;
- Reliant finds that an Investigator is not in compliance with this policy or an imposed FCOI management plan.

L. Noncompliance

In the event an Investigator is alleged to have violated the requirements of this policy, the DO shall investigate the allegations and shall make a recommendation to the CIRC as to whether noncompliance occurred and, if found to have occurred, whether a retrospective review is warranted under this policy and, in any case, the appropriate sanction(s) that should be issued in response to the noncompliance. Examples of noncompliance include, but are not limited to, cases where an Investigator has failed to comply with the required process of disclosure by providing incomplete or inaccurate information, and instances where an Investigator has failed to adhere to a prescribed conflict management procedure. The CIRC shall consider the recommendation of the DO and, after internal discussion and discussion with the Chief Medical Officer of any possible sanction(s), will issue its findings and response. Possible sanctions for noncompliance with this policy include, but are not limited to: Verbal sanction, Written sanction, Suspension of the research project, Termination of the research project, Suspension of research privileges at Reliant, Termination of research privileges at Reliant, Termination of employment.

In the event a sanction is issued pursuant to this policy, the sanctioned individual shall have the right to appeal the sanction action in accordance with the applicable Reliant policies and procedures related to the appeal of disciplinary action.

M. Record Retention

Records of all financial disclosures and actions taken by Reliant with respect to each conflicting interest will be maintained for 3 years from the date of study closure as designated by the

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applicable study IRB or the date the final expenditures report is submitted to the PHS, whichever is later.

Written by: Robert Wood Date: 1-DEC-2015
Director of Research

Approved by: MS STEELY Date: 12/8/15
Acting Chief Medical Officer

ATTACHMENT A

**Reliant Medical Group
Disclosure Statement**

PHS Funded Activities Only

This Disclosure Statement must be completed by each Investigator who is or will potentially be responsible for the design, conduct, or reporting of research activities that are PHS funded at Reliant Medical Group (Reliant) or of research activities in which Reliant is participating. The Disclosure Statement should be completed and returned to Reliant's Research Department with any research project proposal, and annually thereafter. Please see Reliant's policy on Financial Conflicts of Interest in PHS Funded Research for further information and guidance.¹ This policy is also posted on the website (Patients/Research). If you have any questions, please contact the Reliant Research Department at 508-595-2193 (ext. 62193) or by email at Ellen.Trencher@reliantmedicalgroup.org.

I. Investigator Information

Investigator Name: _____
Department: _____
Phone Number: _____
Role in Study: _____
Principal Investigator Name (if different): _____

II. Study Information

Title of Protocol: _____

Sponsor or awarding agency providing support for the research²: _____

Name of the product or technology that is the focus of the study or that is being used in the Study (if applicable): _____

Name of the company that owns, makes, or licenses the product or technology being used in the Study (if applicable): _____

¹ Capitalized and underlined terms utilized in this form are defined in the Financial Conflicts of Interest in PHS Funded Research. Some definitions are reproduced in this form for reference purposes.

² Sponsor may be a company, foundation, individual or any entity that provides support for the research, which may include providing funds, drugs, devices, or other resources. An awarding agency may be NIH, CDC or any of the other PHS funding agencies or any other Federal, state or local government agency.

III. Disclosures

A. FINANCIAL INTERESTS

If you check “yes” for any of the following questions, please complete the Outside Activities Reporting Form.

1. OUTSIDE COMPENSATION.

In the last 12 months did you, your spouse or dependent children receive outside compensation that reasonably appears to be related to your institutional responsibilities?³

Yes No

Outside compensation includes salary and any payment for services not otherwise identified as salary, e.g., consulting fees, “in kind” compensation, sponsored travel, paid authorship fees, royalties or honoraria or entitlement to the same. Outside compensation does not include the following: (i) salary or other remuneration paid by your Medical Group; and (ii) income from seminars, lectures, teaching engagements, service on advisory committees or review panels that are 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)⁴, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

2. REIMBURSED OR SPONSORED TRAVEL. (PHS only)

In the last 12 months did you, your spouse or dependent children engage in reimbursed or sponsored travel that reasonably appears to be related to your institutional responsibilities?

Yes No

Reimbursed or sponsored travel is that which is paid on your behalf (or on behalf of your spouse or dependent children) and not reimbursed to the Investigator so that the exact monetary value may not be readily available. Reimbursed or sponsored travel does not include travel expenses that are 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 Institutional responsibilities are defined in the Financial Conflicts of Interest in PHS Funded Research policy as your professional responsibilities on behalf of RELIANT. These may include, for example, activities such as clinical care, research, research consultation, teaching and professional practice; and other activities such as serving on an RELIANT committee or board.

⁴ 20 U.S.C. 1001(a)

3. **EQUITY INTERESTS**

In the last 12 months did you, your spouse or dependent children hold equity interests in a publicly or non-publicly traded entity that reasonably appears to be related to your institutional responsibilities?

Yes No

Equity interests include any stock or stock options or other ownership interests. Equity interests do not include income from investment vehicles, such as mutual funds and retirement accounts, as long as you, your spouse, or dependent children do not directly control investment decisions.

4. **INCOME IN CONNECTION WITH INTELLECTUAL PROPERTY (IP) RIGHTS.**

In the last 12 months did you, your spouse or dependent children receive or royalties other income in connection with intellectual property?

Yes No

This does not include any royalties or other income paid by your Medical Group to you in conjunction with any IP rights assigned to your Medical Group and agreements to share royalties with you.

B. LEADERSHIP ROLES

Do you now hold, anticipate holding, or in the last 12 months have you held, a Leadership Role⁵ with any entity?

Yes No

If you answered yes to the Leadership Role question, please list below the entities in which you hold a Leadership Role and briefly describe the role you hold:

⁵ "Leadership role" includes "employment, consulting in any administrative or executive capacity, or serving as (i) a member of a board of trustees or board of directors, (ii) an officer, or (iii) a member of an advisory committee, advisory board, or subcommittee of a board of trustees or of a board of directors, whether remunerated or non-remunerated.

III. Relationship of Financial Interests Reported in the Outside Activities Reporting Form to Proposed Research

1. Is an entity for which you have reported a financial interest (“reported entity”) the sponsor of the proposed study?
 Yes **No** If yes, entity name: _____
2. Is a reported entity a prime award or subaward recipient, collaborator or contractor for this study?
 Yes **No** If yes, entity name: _____
3. Is a reported entity supplying materials, personnel, data or other support for this study?
 Yes **No** If yes, entity name: _____
4. Does this study investigate, significantly use or otherwise directly impact a product, device, drug, compound, technique, algorithm, or system of any reported entity?
 Yes **No** If yes, entity name: _____
5. Is this study designed to validate any product, device, drug, compound, technique, algorithm, or system owned, licensed or marketed to a reported entity?
 Yes **No** If yes, entity name: _____
6. Will the design, results, or publication of this study affect the compensation paid to you by a reported entity?
 Yes **No** If yes, entity name: _____
7. To the best of your knowledge, could the design, results or publication of this study affect the value of the equity or other financial interest of the reported entity?
 Yes **No** If yes, entity name: _____
8. Is the scope of any work you provide to a reported entity of the same nature as or significantly overlap with the work to be performed during the study?
 Yes **No** If yes, entity name: _____
9. Is there a relationship between your acquisition of equity in or receipt of income from a reported entity and this study?
 Yes **No** If yes, entity name: _____
10. Please provide a brief explanation of any affirmative answers provided above:

IV. Training

By checking the box below, you are confirming that you have completed the mandatory training on conflicts of interest available via CITI for all research subject to the PHS regulations.

Yes **No** **NOT APPLICABLE** (the proposed research is not subject to PHS regulation)

V. Principal Investigators Only

If you are the Principal Investigator acting on behalf of Reliant, you are responsible for identifying all Investigators on the research project that are affiliated with Reliant and to ensure

that each such Investigator submits a Disclosure Statement as required by Reliant's Financial Conflict of Interest in PHS Funded Research policy. An Investigator includes the project director and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research. An Investigator may include, for example, significant collaborators or consultants. Please list name, role and email address and phone number of all those responsible for the conduct, design or reporting of the research:

VI. Acknowledgement for PHS funded research

By checking the box below, you confirm that you have updated your Outside Activities Report to reflect your Significant Financial Interests for the previous twelve (12) months (including, reporting of all Sponsored/Reimbursed Travel)

- I confirm that my Outside Activities Report is updated and acknowledge that I have a responsibility to update my Outside Activities Report within thirty (30) days of acquiring a new Significant Financial Interest.

CERTIFICATION

By executing below, I hereby certify the following:

- a. I have fully and to the best of my ability accurately completed this Disclosure Statement.
- b. I have reviewed and am in compliance with Reliant's policy on Financial Conflicts of Interest in PHS Funded Research.
- c. I will update this Disclosure Statement (and my annual Outside Activities Reporting Form) within thirty (30) days, if at any time, my circumstances change such that the information provided in this Disclosure Statement is inaccurate or incomplete⁶.
- d. I accept the obligation to comply with all applicable state and federal laws and regulations, institutional policies and procedures, and the requirements and determinations of the reviewing IRB with respect to this research.
- e. I understand that this form does not take the place of my obligation to fill out other financial disclosures or conflict of interest forms required by the reviewing IRB, sponsor, prime institutions or others; I agree to forward a copy of any such other forms that I complete to the Research Department at the time that they are submitted to the external entity.

SIGNATURE

Signature of Investigator

Date

⁶ 42 CFR Part 50 subpart F requires each Investigator who is participating in PHS-funded research to submit an updated disclosure of Significant Financial Interest to the Institution's designated official within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest.

ATTACHMENT B

Outside Activities Reporting Form

Please be advised that you may be requested to provide additional information based on the information provided on this form. Please submit this form to the Reliant's Director of Research at Ellen.Trencher@Reliantmedicalgroup.org or via fax at 508-595-2225. If you have any questions, please call the Research Department at 508-595-2193.

This information is being requested in accordance with federal regulations and the Reliant policy on Financial Conflicts of Interest in PHS Funded Research and must be filled out if you are now or will potentially be **responsible for the design, conduct, reporting of research activities** at Reliant. This initial disclosure is due no later than the time of you submit your research proposal.

Personal and Research Information

Name: _____ **Department:** _____
Medical Group: _____ **Phone:** _____
Research Project Title: _____ **Email:** _____

DISCLOSURES

I. OUTSIDE COMPENSATION

If you checked "yes" on your disclosure form, please provide the following information with regard to all outside compensation that was received by you, your spouse or your dependent children in the last 12 months. Outside compensation does not include the following: (i) salary or other remuneration paid by Reliant; and (ii) income from seminars, lectures, teaching engagements, service on advisory committees or review panels that are 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. If more space is needed, please attach additional pages of this form.

Receiver of Outside Compensation (Name, relationship to you)	Reason for Compensation (e.g., lecture fees, consulting fees, authorship fees, advisory or other committee or board fees)	Short description of services provided	Paid By	Amount in the last 12 months (Dollars)

Are any of the above Outside Compensation interests reasonably related to the research (Y/N)? _____

If so, which interests?

II. REIMBURSED OR SPONSORED TRAVEL (for PHS-Funded Research only)

If you checked “yes” on your disclosure form, please provide the following information with regard to all reimbursed or sponsored travel that was paid to you, your spouse or dependent children in the last 12 months. You may also list travel that is planned but not yet complete for which you have already been paid. If more space is needed, please attach additional pages of this form.

Traveler (Name, relationship to you)	Month and Year of Trip	Trip Sponsor or Organizer	Duration of Trip	Destination	Purpose of Trip (e.g., Scientific meeting, research collaboration, professional service, professional development)

Are any of the above Reimbursed or Sponsored Travel interests reasonably related to the research (Y/N)?

If so, which interest(s)?

Please note that Federal Regulation requires you to submit a new form within **30 days** from completion of any new travel not listed above.

III. EQUITY INTERESTS

If you checked "yes" on your disclosure form, please provide the following information with regard to all equity interest(s) held by you, your spouse or your dependent children in the last 12 months in a publicly or non-publicly traded entity. Equity interests include any stock or stock options or other ownership interests. Equity interests do not include income from investment vehicles, such as mutual funds and retirement accounts, as long as you, your spouse, or dependent children do not directly control investment decisions. If more space is needed, please attach additional pages of this form.

Holder of Equity Interest (Name, relationship to you)	Type (stock, stock options)	If stock options, are they currently exercisable? (y/n)	Name of Entity Stock/Options are Held in	Entity publicly traded on a stock exchange? (y/n)	Number of Shares	Value if Publicly Traded	Percentage Ownership

Are any of the above Equity interests reasonably related to the research (Y/N)? _____

If so, which interest(s)?

IV. ROYALTIES/INCOME IN CONNECTION WITH INTELLECTUAL PROPERTY (IP) RIGHTS

If you checked “yes” on your disclosure form, please provide the following information with regard to all royalties or other income received by you, your spouse or your dependent children in the last 12 months in connection with IP (e.g. patents, copyrights), please fill out the chart below, detailing those interests. This does not include IP rights assigned to Reliant and agreements to share in royalties related to those rights. If more space is needed, please attach additional pages of this form.

Receiver of Royalties (Name, relationship to you)	Type (patent, trademark, copyright)	Government ID number	Subject Matter of IP (describe it)	Owned by (name)	Inventor(s) (names)	Total \$ received in the last 12 months

Are any of the above IP interests reasonably related to the research (Y/N)? _____

If so, which interest(s)?

CERTIFICATION

I certify that the above information is complete and true to the best of my knowledge and that I have read Reliant’s policy on Financial Conflicts of Interest in PHS Funded Research .I acknowledge that if my research is PHS-funded that I am responsible for submitting updates to this Outside Activities Report within 30 days of acquiring a new Significant Financial Interest as defined in the Reliant’s Financial Conflict of Interest in PHS Funded Research policy.

SIGNATURE

Signature of Investigator

Date