

Plymouth State University Policy on Financial Conflict of Interest in Research Projects

1. Statement of Need and Purpose

1.1 Externally sponsored research is a vital part of the Plymouth State University (PSU) mission. As this activity grows in sophistication and complexity, it intersects increasingly with industrial explorations and entrepreneurial ventures creating for Investigators (see **section 3.8**) the potential for conflicting interests.

1.2 A financial conflict of interest (FCOI, see **section 3.4**) exists when it can be reasonably determined that an Investigator's personal financial concerns could directly and significantly influence the design, conduct, or reporting of sponsored research activities. Faculty and staff of the University have an obligation to scrupulously maintain the objectivity of their research so as to avoid any conflict of interest.

1.3 PSU has developed this policy to protect the integrity of sponsored research and to comply with federal regulations¹. It is the intent and policy of the University, as an institution of higher education in receipt of federal research support, to comply with present and future regulations. To that end, this policy is subject to further refinements as other rules are published.

1.4 Specifically, the intent of this policy is to identify and eliminate or manage any possible threat to research objectivity at the University. The main components are disclosure of Investigators' Financial Interests (see **section 3.6**) that might be affected by the research, and application of methods to minimize or eliminate the risks associated with such connections. It is not meant to discourage, but rather to safeguard the pursuit and dissemination of knowledge.

1.5 Some conflicts of interest could affect the rights and welfare of human subjects in research. This policy intends to identify and eliminate or manage FCOI in research that could lead to the unethical treatment of research subjects.

2. Applicability

2.1 This policy applies to any PSU employee responsible for the design, conduct, or reporting of research activities funded or proposed for funding at the University by external sources. This includes both federal and nonfederal externally funded research, regardless of funding source. Additionally, where this policy specifies research funded, or proposed funding, by the Public Health Services (PHS), PHS referenced sections also apply to other organizations that require compliance with the PHS financial conflict of interest in research regulations

For PHS funded research, this policy also applies to the investigator's immediate family, which is defined as his/her spouse or domestic partner and dependent children.

2.2 Investigators are responsible for ensuring that all participants in a project who are responsible for the design, conduct, or reporting of the research disclose any Significant Financial Interests (see

section 3.15) that would reasonably appear to be affected by the research. Individuals who begin work on an established project through reallocation of effort, hiring, transfer, promotion, etc., and thereby take on a responsible position in a project, must also disclose any such Significant Financial Interests.

2.3 Collaborators, sub-contractors, sub-recipients, and visiting scientists must either comply with this policy or provide a certification to the Office of Research Administration (ORA) that their institutions are in compliance with pertinent federal policies and that they in turn are in compliance with their own institutional policies.

3. Definitions

3.1 Conflict Management Plan: A detailed set of steps which are proposed to manage, reduce, or eliminate the financial conflict of interest (see **section 5.3**).

3.2 Disclosure Statement: An investigator's statement recorded in the Disclosure Statement for Financial Conflict of Interest in Research Projects form, which reveals or admits to the existence of Significant Financial Interests (see **section 3.15**) in potential or existing research projects at the University.

3.3 Disclosure Review Committee (DRC): The PSU committee charged with protecting the integrity of PSU's externally-funded research enterprise, and PSU employees who engage in externally-funded research, by identifying and resolving FCOI in research. The DRC conducts its duties in a manner intended to promote, not hinder, research relationships. (See **sections 5 and 8** for DRC membership and responsibilities.)

3.4 Financial Conflict of Interest (FCOI): A Significant Financial Interest (see **section 3.15**) that could directly and significantly affect the design, conduct, or reporting of research.

3.5 FCOI Report: PSU's report of a financial conflict of interest to a sponsor.

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

3.7 HHS: United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

3.8 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 funded by external sources, or proposed for such funding, which may include, for example, collaborators or consultants.

3.9 Manage: Taking action to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

3.10 PHS: The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

3.11 PHS Awarding Component: The organizational unit of the PHS that funds the research that is subject to 42 CFR 50 subpart F.

3.12 Public Health Service Act or PHS Act: The statute codified at 42 U.S.C. 201 et seq.

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

3.14 Senior/Key Personnel: The PD/PI and any other person identified as senior/key personnel by PSU in the grant application, progress report, or any other report submitted to the sponsor by PSU.

3.15 Significant Financial Interest (SFI):

3.15.1 A Financial Interest consisting of one or more of the following interests of the investigator (and those of the Investigator's spouse or domestic partner, and dependent children) that could reasonably appear to be affected by the activities proposed for funding:

3.15.1.1 Any current Financial Interest of the Investigator (and his/her spouse or domestic partner, and dependent children) that could reasonably appear to be affected by the activities proposed for funding; or

3.15.1.2 Any Financial Interest held by the Investigator (and his/her spouse or domestic partner, and dependent children) in a business entity (company, corporation, or other enterprise) whose Financial Interests might reasonably appear to be affected by such activities.

3.15.2 Specifically, SFIs might include, but are not limited to, any of the following:

3.15.2.1 Anything of significant monetary value, including salary or other payments for services such as consulting fees or honoraria;

3.15.2.2 Direct equity interests such as stock, stock options, or ownership interests;

3.15.2.3 With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve 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 (e.g., consulting fees, honoraria, paid authorship); 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;

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

3.15.2.4.1 Intellectual property rights and interests owned by the Investigator such as patents, copyrights, and royalties from such rights and interests. This does not include intellectual property rights and interests assigned to PSU nor royalty income received from PSU per the PSU Intellectual Property Policy.

3.15.2.4.2 Any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and the Investigator's spouse or domestic partner, and dependent children, and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities that occurred in the twelve months preceding the disclosure.

3.15.2.4.2.1 This (3.15.2.4.2) disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

3.15.2.4.2.2 This disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

3.15.2.4.2.3 The institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

3.16 Significant Financial Interests Do Not Include:

3.16.1 Salary, royalties, or other remuneration paid by PSU to the Investigator if the Investigator is currently employed or otherwise appointed by PSU, including intellectual property rights assigned to PSU and agreements to share in royalties related to such rights;

3.16.2 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;

3.16.3 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, non-profit entities; or

3.16.4 Income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

3.16.5 Small Business Innovation Research (SBIR) Program: The extramural research program for small businesses that is established by the Awarding Components of PHS and certain other Federal agencies under Public Law 97–219, the Small Business Innovation Development Act, as amended. SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102–564.

4. Disclosure Process

4.1 Any employee responsible for the design, conduct, or reporting of research activities (Investigator) funded or proposed for funding at PSU by external sources must disclose all current SFIs that would reasonably appear to be affected by the research.

4.2 Each Investigator who has a SFI possibly affected by the research must complete a PSU Disclosure Statement for Financial Conflict of Interest in Research Projects form and attach any requested supporting documentation. The form and supporting documentation should be submitted in a sealed envelope marked "Confidential" to the ORA. If the Disclosure Statement indicates involvement of human subjects in the research, the ORA will notify the chairperson of the Institutional Review Board for the Protection of Human Subjects in Research (IRB) so the situation may be considered, and, if appropriate, addressed by the IRB.

4.3 Each investigator who is participating in PHS-funded research must submit to PSU an updated Disclosure Statement for Financial Conflict of Interest in Research Projects form at least annually (fiscal year [July 1 – June 30]) during the period of the award. Such disclosure shall include any information that was not disclosed initially to PSU or in a subsequent Disclosure Statement (e.g., any FCOI identified on a PHS-funded project that was transferred from another institution), and shall include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

4.4 All SFIs must be disclosed prior to the time a proposal is submitted to an external sponsor. Investigators must update within thirty (30) days all financial disclosures during the period of the award as new reportable SFIs are obtained.

4.5 An investigator may choose to disclose other financial or related interests that might present an actual, potential, or perceived conflict of interest. Disclosure can be a key factor in protecting an individual's reputation and career from potentially harmful allegations of misconduct.

4.6 All Disclosure Statements and related documents are considered sensitive information. As such, they will be treated as confidential and will not be revealed outside the DRC and its staff without the Investigator's consent except: in response to a request from a sponsor, under the public accessibility requirements of section 11, or pursuant to a judicial order or lawfully issued subpoena. PSU will make reasonable efforts to notify the Investigator of any judicial order or lawfully issued subpoena in advance of disclosure of this information, unless the order is from a federal grand jury or is for law enforcement purposes and its terms prohibit PSU from disclosing its existence or contents.

5. Review of Disclosures

5.1 The Disclosure Review Committee (DRC) will review all Disclosure Statements. The DRC will consist of the **Provost**, Associate Vice President for Finance & Administration, Director of the Center for Research & Innovation, a representative from the Office of Research & Administration, and the Faculty Speaker, or their designee.

5.2 The DRC will be responsible for determining whether the Significant Financial Interests of the Investigator could reasonably be expected to affect the design, schedule, conduct, or reporting of the activities funded or proposed for funding, and, if so related, whether the SFI represents a FCOI. An investigator's SFI is related to the research when the DRC reasonably determines that the SFI could be affected by the research; or is in an entity whose Financial Interest could be affected by the research. The DRC may involve the Investigator in its determination of whether a SFI is related to the research. A FCOI exists when the DRC reasonably determines that the SFI could directly and meaningfully affect the design, conduct, or reporting of the research. The DRC may request additional clarifying information from the individual which will be treated as non-public information to the extent allowed by law.

5.3 If a FCOI, the DRC shall request that the Investigator submit a proposed Conflict Management Plan that details steps that could be taken to manage, reduce, or eliminate the FCOI. The DRC shall review the proposed Conflict Management Plan and either approve it as is or add conditions or restrictions to ensure that any conflict is managed, reduced, or eliminated. Such conditions or restrictions may include, but are not limited to, the following:

- 5.3.1** Public disclosure of FCOI (e.g., when presenting or publishing the research);
- 5.3.2** Monitoring of the research by independent reviewers;
- 5.3.3** Modification of the planned activities (possibly subject to sponsor approval);
- 5.3.4** Disqualification from participation in all or part of the project;
- 5.3.5** Divestiture of Significant Financial Interests;
- 5.3.6** Severance of relationships creating conflict;
- 5.3.7** For research involving human subjects, disclosure of FCOI directly to research subjects.

5.4 In all cases, resolution of the conflict or establishment of an acceptable Conflict Management Plan must be achieved before expenditure of any funds under an award to PSU.

5.5 When an Investigator, who is new to participating in a PHS-funded research project, discloses a SFI or an existing Investigator discloses a new SFI, PSU shall:

- i. review the disclosure of the SFI within sixty (60) business days;
- ii. determine whether it is related to PHS-funded research;
- iii. determine whether a FCOI; and, if so, implement, on at least an interim basis, a Conflict Management Plan that shall specify the actions that have been and will be taken to manage such FCOI.

Depending on the nature of the Significant Financial Interest, PSU may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of its review.

5.6 Whenever PSU identifies a SFI that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by PSU during an ongoing PHS-funded research project (e.g., was not reviewed or reported timely by a sub-recipient), PSU shall:

- i. review the SFI within sixty (60) business days; determine whether it is related to PHS-funded research;
- ii. determine whether a FCOI exists; and, if so implement, on at least an interim basis, a Conflict Management Plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward.

5.6.1 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 PSU to constitute a FCOI; failure by PSU to review or manage such a FCOI; or failure by the Investigator to comply with a Conflict Management Plan, within 120 business days of the its determination of noncompliance, PSU shall complete a Retrospective Review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research conducted during the period of the noncompliance was biased in the design, conduct, or reporting of such research.

5.6.2 PSU shall document the Retrospective Review. Such documentation shall include, but not necessarily be limited to, the following key elements:

- i. Project number;
- ii. Project title;
- iii. PD/PI or contact PD/PI if a multiple PD/PI model is used;
- iv. Name of the Investigator with the FCOI;
- v. Name of the entity with which the Investigator has a FCOI;
- vi. Reason(s) for the Retrospective Review;

- vii. Detailed methodology used for the Retrospective Review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- viii. Findings of the Retrospective Review;
- ix. Conclusions of the Retrospective Review.

5.6.3 Based on the results of the Retrospective Review, PSU shall update the previously submitted FCOI Report if appropriate, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, PSU is required to notify the PHS Awarding Component promptly and submit a Mitigation Report. The Mitigation Report must include, at a minimum, the key elements documented in the Retrospective Review above and a description of the impact of the bias on the research project and PSU's plan of action 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 claim of actual or future harm; analysis of whether the research project is salvageable). Thereafter, PSU must submit an FCOI Report annually.

Depending on the nature of the FCOI, PSU may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of PSU's Retrospective Review.

6. Appeals

6.1 Appeal of the DRC's decision may be made to the PSU President. The President will consult with the Investigator and the DRC (including the Provost). The PSU President will make a final determination, which shall be final and binding upon all parties.

7. Compliance

7.1 As part of the Disclosure Statement, each Investigator must certify that if the DRC determines a conflict exists, the Investigator will adhere to all conditions or restrictions imposed upon the project and will cooperate fully with the individual(s) assigned to monitor compliance.

8. Enforcement

8.1 Failure to properly disclose relevant SFIs or to adhere to conditions or restrictions imposed by the DRC and Conflict Management Plan will be considered a deviation from accepted standards of conducting research at PSU.

8.2 The DRC will investigate alleged violations of this policy, and will make recommendations for action to the PSU President. Breaches of policy include failure to file the necessary Disclosure Statements; knowingly filing incomplete, erroneous, or misleading Disclosure Statement forms; or failure to comply with Conflict Management Plan procedures prescribed by the DRC. If the President determines that the policy has been violated, he/she may impose sanctions including,

but not limited to, notification of sponsor and termination of award; formal admonition; a letter to the Investigator's personnel file; and suspension of the privilege to apply for external funding.

9. Records

9.1 The ORA will maintain records of all Disclosure Statements, associated documents, and DRC activities securely and confidentially (see **section 4.5** of this policy for exceptions).

9.2 All records will be maintained for three years following termination or completion of the project or resolution of any government action involving the records.

9.3 Records will not be routinely provided to sponsors unless such is an agency requirement, the agency submits a written request, or PSU is unable to satisfactorily manage an actual or potential FCOI. The ORA will be responsible for communications with sponsors.

10 Reporting to PHS and PHS Oversight

10.1 Prior to PSU's expenditure of any funds under a PHS-funded research project, PSU, via the ORA, shall provide to the PHS Awarding Component an FCOI Report regarding any Investigator's SFI found to be conflicting. In cases in which PSU identifies a FCOI and eliminates it prior to the expenditure of PHS-awarded funds, PSU shall not submit an FCOI Report to the PHS Awarding Component.

10.2 For any SFI that PSU identifies as conflicting subsequent to the PSU's initial FCOI Report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), PSU shall provide to the PHS Awarding Component an FCOI Report regarding the FCOI within sixty (60) business days and ensure that PSU has implemented a Conflict Management Plan in accordance with 42 CFR 50 subpart F.

10.3 Where a FCOI Report involves a SFI that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed or managed by PSU (e.g., was not reviewed or reported in a timely manner by a sub-recipient), PSU also is required to complete a Retrospective Review to determine whether any PHS-funded research conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of such research. Additionally, if bias is found, PSU is required to notify the PHS Awarding Component promptly and submit a Mitigation Report to the PHS Awarding Component.

10.4 In FCOI Reports required in **sections 10.1** and **10.2** of this policy, PSU shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the FCOI and to assess the appropriateness of PSU's Conflict Management Plan. Elements of the FCOI Report shall include, but are not necessarily limited to, the following:

- i. Project number;
- ii. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- iii. Name of the Investigator with the FCOI;
- iv. Name of the entity with which the Investigator has a FCOI;

- v. Nature of the Financial Interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- vi. Value of the Financial Interest (using 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;
- vii. A description of how the Financial Interest relates to the PHS-funded research and the basis for PSU's determination that the Financial Interest conflicts with such research;
- viii. A description of the key elements of PSU's Conflict Management Plan, including:
 - a. Role and principal duties of the conflicted Investigator in the research project;
 - b. Conditions of the Conflict Management Plan;
 - c. How the Conflict Management Plan is designed to safeguard objectivity in the research project;
 - d. Confirmation of the Investigator's agreement to the Conflict Management Plan;
 - e. How the Conflict Management Plan will be monitored to ensure Investigator compliance;
 - f. Other information as needed.

10.5 For any FCOI previously reported by PSU with regard to an ongoing PHS-funded research project, PSU shall provide to the PHS Awarding Component an annual FCOI Report that addresses the status of the FCOI and any changes to the Conflict Management Plan for the duration of the PHS-funded research project. The annual FCOI Report shall specify whether the financial conflict is still being managed or explain why the FCOI no longer exists. PSU shall provide an annual FCOI Report to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

10.6 If the failure of an Investigator to comply with this policy or Conflict Management Plan appears to have biased the design, conduct, or reporting of the PHS-funded research, PSU shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component may consider the situation and take appropriate action or refer the matter to PSU for further action, which may include directions to PSU on how to maintain appropriate objectivity in the PHS-funded research project.

10.7 The PHS Awarding Component and/or HHS may inquire at any time before, during, or after award into any Investigator's Disclosure Statement and PSU's review (including any Retrospective Review) of, and response to, such disclosure, regardless of whether the disclosure resulted in PSU's determination of a FCOI. PSU is required to submit, or permit on site review of, all records pertinent to compliance with 42 CFR 50 subpart F. To the extent permitted by law, HHS will maintain the confidentiality of all records of Financial Interests. On the basis of its review of records or other information that may be available, the PHS Awarding Component may decide that a particular FCOI will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed, or that PSU has not managed the FCOI in accordance with 42 CFR 50

subpart F. The PHS Awarding Component may determine that imposition of special award conditions under 45 CFR 74.14 and 92.12, or suspension of funding or other enforcement action under 45 CFR 74.62 and 92.43, is necessary until the matter is resolved.

10.8 In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a FCOI that was not managed or reported by PSU as required by 42 CFR 50 subpart F, PSU shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

10.9 PSU may require the reporting of other FCOI to PHS as PSU deems appropriate.

11 Public Accessibility

11.1 PSU shall ensure public accessibility via a written response to any requestor within five (5) business days of receipt of a request by the Provost for information concerning any SFI disclosed to PSU that meets the following three (3) criteria:

- i. The SFI was disclosed and is still held by the senior/key personnel as defined by this policy;
- ii. PSU determines that the SFI is related to PHS-funded research;
- iii. PSU determines that the SFI is a FCOI.

11.2 The information that PSU will make available via a written response to any requestor within five (5) business days of receipt of a request by the Provost, shall include, at a minimum, the following:

- i. The Investigator's name;
- ii. The Investigator's title and role with respect to the research project;
- iii. The name of the entity in which the SFI is held;
- iv. The nature of the SFI;
- v. The approximate dollar value of the SFI using 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.

11.3 Information concerning the SFI of an Investigator to **section 6.1** of this policy shall remain available for responses to written requests for at least three (3) years from the date that the information was most recently updated.

12 Training

12.1 Investigators must complete training regarding FCOI, Investigators' responsibilities regarding disclosure of SFIs, and the PHS regulations prior to engaging in research related to any funded grant and at least every four (4) years.

Footnotes

¹*National Science Foundation. Investigator Financial Disclosure Policy. July 11, 1995. 60 FR 35810, Part III; Department of Health and Human Services. Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought. 42 CFR 50 Subpart F (revised August 25, 2011).*

²*This policy pertains to both federal and nonfederal externally sponsored research, regardless of funding source. Additionally, where this policy specifies research funded, or proposed for funding, by the Public Health Services (PHS), PHS referenced sections also apply to other organizations that require compliance with the PHS financial conflict of interest in research regulations*