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# I. General Purpose

The purpose of this policy is to provide guidelines for establishing principled personal outside relationships with other organizations and to establish rules for personal interactions with industry, industry representatives and other vendors throughout Plakous Therapeutics ecosystem (Institution), while remaining in compliance with disclosure, management, and approvals. The Institution supports principled relationships with industry and other organizations in which its employees collaborate. The Institution has adopted this policy to promote the public's trust in the Institution's role in commercial healthcare, research, and education. The policy supports the highest level of integrity of research, safety of human subjects, objectivity of education and the reputations of employees.

## Scope of Policy

This policy applies to all employees and controlled affiliates. Provisions addressing disclosure are specified in sections III and IV.

All exempt employees are required to disclose to the Institution any outside interests, including financial relationships with Industry or other outside organizations, that are related to Institutional duties. This includes disclosure of family members outside interests with entities that do business with Plakous Therapeutics, Inc. The management board will assist Individuals to determine if there is an appearance of conflict of interest, to manage any associated conflicts of interest which might arise in personal outside relationships, and to eliminate those conflicts that cannot be effectively managed.

#### **Responsible Parties**

1. Policy Owner: CEO/Board

- 2. Procedure: CEO
- 3. Supervision: CEO
- 4. Implementation: Supervisor, Director, VP, etc.

## II. Conflict of Interest and Disclosure

The institution requires exempt employees to disclose both research and non-research related outside interests, regardless of the value or income received. Disclosures are collected upon new hire and each April through a self-certification. All annual disclosures will be reviewed by the Individual's department VP/director/manager as defined. In the case of C-level employees, review will be managed by CEO and Board. Please note that leaders are expected to disseminate information about significant conflicts of interest for their direct reports to the appropriate superior leadership.

Upon disclosing outside interests, the Individual will cooperate with the Conflict-of-Interest Review Committee (CIRC) to mitigate potential conflicts of interest, and to manage significant conflicts of interest. Individuals must update their disclosure within 30 days of a substantial change in external relationships or activities.

Additional required disclosures:

- 1. Disclosure of project specific relationships is required with submission of grants, contracts, and regulatory protocols.
- 2. Significant conflicts of interest in clinical research require disclosure of the conflicting relationship to the human subjects enrolled in the project.
- 3. Public disclosure of outside interests is required for all publications (including news releases), presentations (including posters) and approved media contact related to an Individual's outside relationship or financial interests.
- 4. Prior to sponsored professional travel, the Individual will disclose the Sponsor's name, the destination, purpose and duration of travel to management.
- 5. Employees should disclose relationships to patients when such a relationship might appear to be a significant conflict of interest.

# III. Conflict of Interest in Research

The CIRC will evaluate all disclosures of outside interests, including a review of related research projects to determine if a significant financial interest (SFI) may be a conflict of interest on sponsored research and if a FCOI exists.

- If the CIRC determines that a FCOI exists on PHS-funded research, the CIRC will review the design, conduct, and reporting of the research to determine and implement the appropriate management process and Federal reporting in accordance with PHS Regulations *42 CFR, Part 50, Subpart F* and *45 CFR, Part 94*, to protect the credibility and integrity of the Institution and its employees.
- If the CIRC determines that a SFI exists for non-PHS sponsored research, it reviews the design, conduct and reporting to determine and implement the appropriate management process to protect the credibility and integrity of the Institution and its employees.

## Human Subject Research

If a conflict of interest is identified in research involving human subjects, the Institutional Review Board (IRB) and Management Team will conduct their respective reviews in parallel, and the IRB will withhold final approval pending the completion of the CIRC review, resolution of the issues and recommendations for management and board.

Compliance with PHS Regulation 42 CFR, Part 50, Subpart F and 45 CFR, Part 94 Prior to the expenditure of funds and within 60 days of any subsequently identified FCOI on PHS-funded research:

- 1. The Institution shall adhere to its publicly available policy and provide reports regarding identified FCOI to the PHS Awarding Component in accordance with the Institution's own standards and within the timeframe prescribed by this regulation.
- Designate an Institutional official(s) to solicit and review disclosures of Financial Interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research. The designated official is responsible for determining if a significant Financial Interest exists, and whether or not it constitutes a Financial Conflict of Interest per PHS Regulations 42 CFR, Part 50, Subpart F and 45 CFR, Part 94.
- 3. The Institution will ensure that each Investigator is informed of its policy on FCOI, the Investigator's responsibilities regarding disclosure of SFI's, and of these regulations. Each Investigator is to complete training regarding FCOI requirements prior to engaging in research related to any PHS-funded contract and at least every four years, and immediately when any of the following circumstances apply:
  - a. The Institution revises its FCOI policies or procedures in any manner that affects the requirements of Investigators,
  - b. An Investigator is new to the Institution,
  - c. The Institution finds that an Investigator is not in compliance with the Institution's FCOI policy or management plan.
- 4. If an Investigator carries out PHS-funded research through a subrecipient (e.g., subcontractors, or consortium members), the Institution will take reasonable steps to ensure subrecipient Investigator compliance through:
  - a. A written agreement with the subrecipient that establishes whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.
  - b. The CIRC will provide FCOI reports to the PHS Awarding Component regarding all FCOI of all subrecipient Investigators consistent with this regulation.
- 5. If an Investigator's SFI is related to PHS-funded research:
  - a. The CIRC determines if the SFI could be affected by the PHS- funded research or is in an entity whose financial interest could be affected by the research.
  - b. The CIRC determines if a FCOI exists when the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
- 6. Identification of an FCOI initiates development and implementation of a management plan by the CIRC and, if necessary, a retrospective review and mitigation report pursuant to §94.5(a).
- 7. The Institution provides initial and ongoing FCOI reports to the PHS awarding component as required pursuant to § 94.5(b).
- 8. The Institution maintains records relating to all Investigator disclosures of financial interests, the CIRC's review of, and response to, such disclosures, and all actions under Institutional policies or

retrospective review, if applicable, for at least three years from the date of the final expenditure of funds.

- 9. The Institution maintains enforcement mechanisms and provides sanctions and other administrative actions to ensure Investigator compliance as appropriate.
- 10. The Institution ensures public accessibility, via written response to any requestor within five business days of a request, for information concerning any SFI disclosed to the Institution that meets the following three criteria:
  - a. The SFI was disclosed and is still held by Investigator,
  - b. The Institution determines that the SFI is related to the PHS-funded research,
  - c. The Institution determines that the SFI is a FCOI
- 11. The information available via written response to any requestor within five business days of a request shall include, at a minimum, the following: Investigator's name,
  - a. Investigator's title and role with respect to the research project,
  - b. Name of the entity in which the SFI is held,
  - c. Nature of the SFI, and
  - d. Approximate dollar value of the SFI, or a statement that the interest is one whose value cannot be readily determined through to public prices or other reasonable measures of fair market value.

# IV. Permitted Outside Employment/ External Professional Relationships Requiring Prior Approval

- Outside employment is evaluated primarily by departmental leadership through prior approval requests and in compliance with the Policy on Conflicts of Commitment. See section A.
- Certified continuing education is either evaluated through the institution's CME Office or must adhere to their same policies if certified outside the institution. See section B.
- Under the guidance of the Conflict-of-Interest Review Committee (CIRC), the COI Office evaluates
  - requests for non-certified education funded by Industry, see section C.
  - o requests for travel funding received by third party institutions, see section D
  - o other reported outside relationships, including equity in start-up companies, section E.

For prior approvals, the COI Office may grant approval based on guidelines established by the CIRC, or may determine that a request needs additional review by the CIRC.

#### **Outside Employment**

Individuals who wish to undertake outside employment (generally requiring considerable effort, earning equity or income, and/or related to institutional responsibilities), including but not limited to consulting, expert witness activities, personal businesses and advisory boards must obtain prior approval from his or her departmental leadership. Final review for COI compliance is available through the CIRC, at the request of the department leader.

## Attending, Organizing or Speaking for Non-Certified Educational (non-CE) Events

#### Sponsored by Industry

Unless covered under a contractual agreement previously approved by his/her supervisor, an Individual who wishes to attend, organize or conduct speaking for a non-CE meeting, conference, or other activity that is fully or partially sponsored by a third party institution must follow the guidelines for the specific activity found in Appendix B and complete the appropriate prior approval request documents.

## Receiving Travel Funding from a Third Party Institution Sponsor for Special Circumstances

Any Individual who has been offered travel funding from an Industry sponsor to view capital equipment or for specialized training on capital equipment/devices must obtain prior approval from his or her supervisor and the COI Office.

Prior approval is required if the travel meets one of the following circumstances:

- 1. To view capital equipment in situ if the equipment is being considered for purchase by Institution; must submit request for prior approval by the VP/Director.
- 2. To participate in initial and ongoing education necessary to operate or use products and devices which require specialized expertise and are currently being used at the Institution; must submit request for prior approval by the VP/Director.

Prior approval is not required if the travel meets one of the following requirements:

- 1. For reimbursement for travel to provide contractual services, such as approved consulting that has been approved by VP/Director through an Outside Employment Request.
- 2. To participate in meetings directly related to the initiation of sponsored research or ongoing sponsored research covered under a research agreement.
- 3. Receipt of travel funds from scientific societies, even if Industry is the source of the funds, provided that the society controls the selection of the recipient of the travel support.

#### Licenses, Royalties, and Equity and Engaging in a Start-up Company

Individuals must report proposed outside professional relationships with third party Institutions and other entities related to their areas of expertise and professional duties, including start-up companies, in which they expect to receive royalties or equity, regardless of the value. These relationships must be reported in advance to the appropriate VP/Director for review and approval prior to agreeing to, engaging in, or accepting income for the activities.

# V. Prohibited Personal Professional External Activities with Industry and Other Entities

#### Promotion of Vendors Products

Individuals may not participate in promotional events for third party institutions or vendors designed to influence purchasing or prescribing decisions without approval from VP/Director.

#### Advising for Investment Companies

Individuals are prohibited from advising representatives of investment companies (including but not limited to investment firms, hedge funds, investment bankers, venture capital firms, and brokerage houses) on the status of areas of research and development, especially non-public information within the realm of the individual's professional expertise or collaborative knowledge, whether by telephone or email, in meetings, or otherwise. Directly or indirectly disclosing material or confidential information from a clinical trial prior to publication to individuals or companies that trade stock or advise such companies based on such information is prohibited.

# VI. Gifts from Industry - see Appendix C

# VII. Industry Access to Facilities, Staff and Trainees - see Appendix D

# VIII. Other Considerations for Employees and Key Officials

## Administrative Actions by Key Officials

Key officials in the Institution include C-level employees, vice presidents, officers, directors. Because of their leadership roles, authority to make important decisions, fiduciary duty to act in the best interests of the Institution, and positions as role models for other Individuals, key officials are held to an even higher standard of ethics, integrity, professionalism, and objectivity in their decisions and conduct. Key officials might not be permitted to engage in some personal, professional relationships with third party institutions that are allowable for others, when actual or perceived conflicts of commitment or interest would result or may have restrictions on their ability to make certain decisions. Key officials should always be aware that their decisions may create institutional conflicts of interest in all missions.

# IX. Penalties for Breach of Policy

Individuals have an obligation to comply with this policy. Examples of conduct that violates this policy includes, but is not intended to be exhaustive:

- Failure to comply with the annual disclosure process by refusal to respond,
- Intentional deception or dishonesty in disclosures,
- Omission of industry relationship disclosures,
- Failure to remedy conflicts of interest,
- Failure to comply with management plan requirements, or
- Repeated failure to seek prior approval for speaking or for organizing or attending non-certified outside activities funded by Industry.

Reports of suspected violations may be made to any of the Individuals listed below, or anonymously through the HR department or executive management. Suspected violations will be investigated and referred to leadership in accordance with Appendix A, Definition of Authority.

Penalties for deliberate violations of this policy will be adjudicated in accordance with applicable disciplinary policies and procedures. Penalties for failure to comply will be commensurate with the breach and may include, but are not limited to:

- Reimbursement to the Institution for misused resources, including salary and/or other forms of institutional compensation and other applicable fines imposed by outside entities,
- Written admonition for placement in Individual's employee file indicating that the individual's good standing has come into question,
- Ineligibility to participate in grant applications, IRB or IACUC applications or on committees,
- Performance improvement counseling
- Dismissal of employment.

If the failure of a research investigator to comply with this policy has, or appears to have, biased the design, conduct, or reporting of PHS-funded research, in accordance with 42 CFR Part 50 Subpart F, Section 50.606 (a) and 45 CFR, Part 94, the Institution must promptly notify the PHS Awarding

Component of the findings and corrective action taken or to be taken. The PHS Awarding Component will consider the situation and may take appropriate action or refer the matter to the Institution for further action, such as determining how to maintain appropriate objectivity in the funded project.

If, in the course of investigating allegations of research misconduct, evidence of violations of the Conflict of Commitment and Conflict of Interest Policy is discovered, the Research Integrity Officer conducting the misconduct investigation may consult with the Conflict-of-Interest Office to determine the need for any additional course of action.

# X. Review/Revision/Implementation

## **Review Cycle**

This policy shall be reviewed by the management at least every three (3) years from the effective date. Office of Record

The CIRC shall maintain this policy.

# XI. Governing Law of Regulations/Guidelines

Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94) http://grants.nih.gov/grants/policy/coi/

Bayh-Dole Act (1980), 37 CFR 401.1-16

http://ecfr.gpoaccess.gov/cgi/t/text/textidx?c=ecfr&tpl=/ecfrbrowse/Title37/37cfr401\_main\_02.tl Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)

http://oig.hhs.gov/fraud/enforcement/cmp/index.asp

"Stark Law" Section 1877 of the Social Security Act 42 U.S.C.

1395nn, https://www.cms.gov/PhysicianSelfReferral/

Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support of CME: Standards to Ensure the Independence of CME Activities

PhRMA http://www.phrma.org/

AdvaMed http://www.advamed.org/MemberPortal/

# XII. Appendix A – Definitions

- A. Authority: reviews, management determinations, final approvals, and sanctions regarding conflicts of commitment will be made in accordance with the table below.
- B. Individual: employee of institution or controlled affiliate who owes a primary duty of loyalty and support to the Institution, including part-time appointments. Family members related by blood, adoption, or marriage are included when considering financial or fiduciary interests.
- C. Institution: Plakous Therapeutics, Inc..
- D. Third Party Institutions: other biomedical, pharmaceutical, supply chain, managed care organizations, and companies that make other products used in the development or manufacture of institution products, or institution research.
- E. Income: the amount of money received during a period of time in exchange for labor or services, from the sale of goods or property, or as a profit from financial investments.
- F. Entity: a for-profit or not-for-profit organization for which an Individual spends considerable time and/or receives income.
- G. Equity: ownership interest of shareholders in a corporation, partnership, or similar organization (includes ownership in non-valued start-up companies)
- H. Conflict of Interest: in professional and scientific endeavors refers to a situation in which financial or other personal considerations may compromise, or have the appearance of compromising, an Individual's professional judgment in conducting or reporting research, patient care, education, for carrying out or directing other types of institutional programs. The bias that may result from such conflicts could impact not only the collection, analysis, interpretation and reporting of data, but also the hiring of staff, the procurement of materials, or the conduct of other activities supporting the institution's objectives.
  - a. Reportable outside activities include, but are not limited to ongoing or repetitive arrangements with outside entities (e.g. consulting, speaking, expert testimony, paid court appearances, laboratory testing, teaching, etc.). Other reportable activities are fiduciary and management roles in organizations outside the Institution, including board of directors, officer, manager, or medical director of a for-profit company, non-profit organization, charitable foundation, or academic society.
  - b. Non-reportable outside activities include writing, membership on peer review panels, visiting professorships or lectureships at academic medical centers, federal and non-federal study section membership, grant review panels, and textbook editorships.
- I. Industry-Sponsored Travel: the occurrence of any reimbursed or industry-sponsored travel (i.e., that which is paid on behalf of the Individual so that the exact monetary value may not be readily available), related to the Individual's institutional responsibilities. This does not apply to travel that is reimbursed or sponsored by the following:
  - a. A federal, state, or local government agency
  - b. An Institution of higher education as defined at 20 U.S.C. 1001(a)
  - c. An academic teaching hospital
  - d. A medical center
  - e. A research institute that is affiliated with an Institution of higher education.
- J. Travel Authorization: a form that serves as the disclosure for Industry-Sponsored Travel and is completed prior to any professional travel. Reimbursed or Industry-Sponsored travel information

must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of travel.

- K. Conflict of Interest Review Committee (CIRC): a committee of C-Level/VP/directors responsible for ensuring that individual and institutional conflicts of interest in research, clinical care, education, purchasing, intellectual property transfers and other institutional missions are identified, managed, or eliminated, in accordance with federal regulations and in the best interests of patients, research subjects, trainees, researchers, employees and the Institution.
- L. Outside Employment: personal contractual services provided for entities outside the Institution for which an individual spends considerable time and/or receives a regular retainer or income. Outside Employment includes, but is not limited to, consulting, scientific advisory board memberships, clinical trial review panels, developing educational materials, teaching, laboratory testing, expert legal testimony, paid court appearances, and legal expert witness consultation activities. Other activities considered Outside Employment are fiduciary and management roles inorganizations outside the Institution, including board member appointments, and serving as an officer, manager, or medical director of a for-profit company, non-profit organization or charitable foundation or an unvalued start-up company.
- M. Outside Interest: a personal professional relationship with any entity, domestic or foreign, public or private, for-profit or non-profit (excluding a Federal agency) with which an Individual has a financial interest or regular time commitment. This includes disclosure of family members 'interests with entities that do business with Plakous Therapeutics or its immediate suppliers and partners.
- N. Financial Interest: anything of monetary value, whether or not the value is readily ascertainable; including, but not limited to, income for services, ownership, equity interest, and fiduciary or management relationships, whether paid or unpaid.
- O. Significant Financial Interest (SFI): a financial interest consisting of one or more of the following interests of an Individual (and those of the Individual's family member):
  - a. With regard to any publicly traded entity, a significant financial interest exists if the value of any income 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.
  - b. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any income received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's family member) holds any equity interest; or
  - c. All royalties and intellectual property rights and interests (e.g., patents, copyrights)

Significant Financial Interest EXCLUSIONS:

- a. Salary, or other income paid by the Institution to the Individual if the Individual is currently employed or otherwise appointed by the Institution,
- b. Any ownership interest in the Institution held by the Individual, if the Institution is a commercial or for-profit organization,
- c. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Individual does not directly control the investment decisions made in these vehicles
- d. 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,

- e. Income from service on advisory committees or review panels for a federal, state or local government agency, 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.
- P. Investigator: the project director or principal Investigator and any other person, regardless of title or position, who the Institution deems is responsible for the design, conduct, or reporting of research, which may include, for example, collaborators or consultants.
- Q. Financial Conflict of Interest (FCOI): a situation in which the Institution, through its designated official(s), reasonably determines that an Investigator's SFI is related to a PHS-funded research project and could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- R. Subrecipient: a party that receives a subaward from a recipient or another subrecipient under a Federal financial assistance award and is accountable to the recipient or subrecipient for the use of the Federal funds provided by the subaward.
- S. Exempt employees: refers to monthly-paid Individuals, including certain special-exempt hourly pay groups of providers such as pharmacists, physical therapists, dieticians, etc. at Plakous Therapeutics.

# XIII. Appendix B - Prior Approval and Guidelines for Attending, Organizing or Speaking for Non-Certified Educational Events Sponsored by Industry

Payments by Third Party Institutions for travel, meals, registrations, honoraria, etc. for an Individual to attend, organize, or speak at a non-CE educational event can compromise the appearance of the integrity in our clinical care. Prior approval promotes awareness of the policy guidelines for each activity, promotes discussion between the individual and his/her supervisor and ensures compliance with the Policy on Conflicts of Interest.

Individuals who wish to attend, organize or speak/provide leadership at a non-CE meeting, conference, or other activity that is fully or partially sponsored by Third Party Institutions must obtain prior approval from his or her supervisor and the CIRC by request via email.

## Attending:

All attendees should follow the guidelines on the document, obtain approval from the appropriate leader, and obtain approval from the CIRC to mitigate the potential for perceived or real conflicts of interest (a departmental individual may complete one document for a group of attendees):

- 1. The main reason for attending the Third Party Institutions-sponsored or supported educational event should be to advance knowledge in the attendee's area of institutional responsibilities with the intention of adding value to patient outcomes and/or institutional service excellence.
- 2. The attendee does not believe the event is a dedicated marketing and promotions program designed by Industry solely to influence purchasing decisions, and the educational value outweighs any marketing influence.
- 3. Attendees may accept invitations to receptions and meals of modest value provided in conjunction with a legitimate educational event when incidental to the education and available for all attendees. The receptions and meals should promote discussions among those attending. Individuals may not attend the reception and accept the meal if they will not be attending the educational component of the event.
- 4. The attendee believes the event contains didactic lecture and/or case-based discussion and/or hands on lab sessions with recognized independent experts in the field who are not primarily employed by the sponsoring vendor.
- 5. The attendee believes that sufficient time is allowed for each activity to advance knowledge and/or train in technique and/or procedure.
- 6. Attendees may not receive a gratuity for attending the educational event, including material gifts, entertainment expenses or honoraria.
- 7. When attending an approved certified educational event and an unanticipated non-CE activity is offered in conjunction with it, attendees do not need to seek additional prior approval to attend but must be mindful of policy guidelines.
- 8. Attendees understand that travel expenses do not extend beyond a reasonable arrival and departure period.
- 9. Attendee(s) do not solicit funding for the activity from vendor representative(s).
- 10. Attendees must obtain approval from their leader and the CIRC prior to attending the educational event.

## Speaking and Leadership

All speakers and leaders should follow the guidelines on the document, obtain approval from the appropriate leader, and obtain approval from the CIRC to mitigate the potential for perceived or real conflicts of interest:

- 1. The Speaker will design the activity to promote evidence-based clinical care, advanced scientific research and/or teach desirable clinical skills or service excellence.
- 2. The Speaker is expected to provide a fair and balanced assessment of the subject and to promote objective scientific and educational activities and discourse.
- 3. The Speaker's purpose at the event is not to act as a company's agent, spokesperson, for marketing representative for the purpose of disseminating company or product information.
- 4. The Speaker prepares the meeting or lecture content and does not use a pre-determined slide set or presentation dictated by the Third Party Institutions to promote or market their product(s) and the company has no contractual right to control the content, excluding FDA required language, review for proprietary information or to grant final approval of the educational presentation. Exceptions to this rule may be granted with prior approval by the CIRC
  - a. to allow Individual participation in FDA-mandated training of providers for a new device or procedure,
  - b. to allow the use of industry-developed illustrative slides that cannot be reasonably duplicated at the institution or,
  - c. to allow an Individual to utilize an unbranded industry slide library to determine and prepare his/her own educational content.
- 5. Financial support by Third Party Institutions will be fully disclosed to the attendees by the Speaker.
- 6. The speaker may accept compensation or honoraria only for the services provided and the compensation must be reasonable and reflect fair market rates. Reasonable reimbursement for related travel and meals may also be accepted by the Speaker.
- 7. The Speaker will instruct vendor representatives not to give material gifts, entertainment expenses, or other compensation to any individuals as a gratuity for attending the activity.
- 8. Individuals must obtain approval from their leader and the CIRC prior to speaking or providing leadership for the educational event.

# XIV. Appendix C - Guidelines on Specific Types of Gifts

## Gifts to Individuals

Personal gifts from Third Party Institutions exceeding \$25 may not be accepted by Individuals. If you have questions about such a gift, please contact the CIRC.

### In-Kind Gifts to the Institution

Gifts to the Institution of equipment, devices, supplies and similar items from Industry for use in education, research or clinical care cannot suggest the expectation of return benefit to the donor, or "quid pro quo". The gift transaction will adhere to company policies.

## Donations to Institution for Philanthropic Events

This policy applies only to philanthropic events that have been approved by executive leadership for the purpose of raising funds for external non-profit organizations. Donations of items intended for raffle or prizes to raise money during philanthropic events must be well-documented and received from the vendor by Plakous' chief organizer of the event. The chief organizer will assure all vendors that their business is not dependent on making donations for such events. Tickets for the charitable event and other reasonably valued items for the event, such as shirts and hats, may be received by employees who are participating in the approved event.

# XV. Appendix D - Guidelines on Third Party Institutions to Employees

#### Access of Marketing Representatives

Marketing Representatives are individuals who:

- 1. Do not conduct business directly with the Institution or any of its affiliates,
- 2. Request access to meet with or provide promotional information to our employees, or
- 3. Seek to do business with these Individuals.

Marketing representatives, individuals that meet the above criteria, will not be provided access by Plakous to phone contacts, emails, or other personal information of its employees or trainees. Marketing Representatives may not offer gifts, meals, or incentives to Plakous employees for referrals to their business. This does not include the representatives for companies which have been endorsed by Human Resources and have a contract to provide services for employees and trainees.

#### Commercial Exhibits (Trade Shows/Vendor Fairs)

A vendor fair is an event intended to promote products and services to be used in the conduct of Institutions business. This policy is not intended to preclude any materials management and/or purchasing department from coordinating vendor displays where several brands of materials are displayed simultaneously for key decision makers to compare them in order to make purchasing or standardization decisions. This policy is not intended to preclude Human Resources or any other department from coordinating vendor displays for benefits or services offered exclusively to employees.

#### News Releases and News Media Contact

Prior to participating in a media event Individuals must disclose to Communications, Marketing and Media (CMM) any potential or actual COI related to personal outside interest in the sponsor of his/her research or in the ownership of a related entity or intellectual property, such as new or experimental drugs, devices or therapies, or of a start-up business. All such disclosures will be reported to the CIRC in compliance with policies.