



**California Northstate University**  
**Policy of Conflict of Interest**  
**Relating to Employees**

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## I. PRINCIPLES

1. California Northstate University (CNU) originally was and continues to be established with private funding by financial sponsors who believe that a great university is defined by its principal goals of education mission, education effectiveness, student success, and long term sustainability.
2. The financial sponsors who are mainly physicians and pharmacists strongly believe that the University will succeed in discharging its mission only if education is second to no other priority and education effectiveness is defined by student outcomes and efficient and appropriate deployment of resources.
3. Accordingly, the financial sponsors expect the University administrators, faculty, and staff (collectively known as the employees) to act not only in the best interest of fulfilling these principal goals, but also to engage in activities such as research, scholarship, service, consulting, and self-development that benefit the students, the University itself, and the larger public. While recognizing the benefit of such activities, CNU is also committed to ensuring that they are conducted properly and consistently, in accordance with the principal goals that are fundamental to the existence and well-being of a university and with the responsible management of the University's business.

At the inception of the institution and to avoid perceived conflicts between education interest and financial interest, the Board of Trustees was reconstituted to perform the oversight and governance of the institution ensuring the fulfillment of education mission, protection of the students, education effectiveness, integrity of scholarly activities, and service to the larger public. The Board of Trustees is composed of members from the community with no financial relationship with the institution and is self-perpetuating with its own nomination and vetting process, and maintains its continuity of function with multi-year staggering terms.

The appointment of a qualified individual who has no financial relationship with the organization which established the College of Medicine to serve as the Dean and Chief Academic Officer, whose responsibilities include the day-to-day operations and management of the on-going medical education further ensures that the principal goals of the University are fulfilled optimally.

In pursuit of its mission California Northstate University has formulated the following policy to identify and address actual conflicts of interest and conflicts of commitment. The fundamental premise of this policy is that each member of the California Northstate community has an obligation to act in the best interest of the University and in furtherance of the University's mission, and must not let financial interest interfere with principal goals of the University. This policy is intended to increase the awareness of all the University employees and the Trustees to the potential for conflicts of interest, and to establish procedures whereby such conflicts may be avoided or properly managed.

### a. Financial Conflict of Interest

A conflict of interest exists when an individual has a significant financial interest (SFI) that could directly and significantly affect his or her University activities. Generally, this will occur when the external interest provides an **incentive** to affect the individual's conduct of his or her University activities and when the individual has the **opportunity** to affect a University decision or other activity (for example, because he or she is the decision-maker or the principal investigator for a

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research project). Conflicts of interest can arise naturally from an individual's engagement with the world outside the University, and the mere existence of a potential or perceived conflict of interest does not necessarily imply wrongdoing on anyone's part. When conflicts of interest do arise, however, they must be recognized, disclosed and either properly managed or eliminated.

Conflicts of interest may exist with respect to University financial decisions in which the individual is involved, for example, regarding investments, loans, purchases or sales of goods or services, and financial accounting decisions. They may also exist with respect to the conduct of research, the care of patients, the protection of human research subjects, and the treatment of students and faculty colleagues. Conflicts may also exist with respect to matters with both financial and non-financial implications, such as decisions about the use of University equipment and facilities and the negotiation of research agreements and license agreements.

#### b. Fundamental Principles

The following principles form the basis that underlies the University's policy on conflicts of interest:

1. When conducting University functions, all employees perform such functions with fiduciary duties: the duty of care (perform the work a prudent individual would do under the same circumstances); the duty of conformance (perform the work in adherence to education mission, policies, standards (including accreditation standards), regulations, laws), and the duty of loyalty (perform the work with the best interest and well-being of the University in mind).
2. The University does not permit any individual with an interest in the financial success of the institution to serve at the University unless the following criteria are met:
  - a. The individual is subject to either supervisorial oversight by an individual of higher authority whose compensation is not directly dependent upon the financial success of the Medical College (known as financially disinterested supervisor) or oversight of the Board of Trustees which collectively has no financial relationship with the College of Medicine.
  - b. The individual is subject to annual performance evaluation by a financially disinterested supervisor whose assessment and opinion are independent or by a Trustees Committee.
  - c. The individual must disclose the presence of financial relationship annually.
  - d. The individual is not the Dean or the Chief Academic Officer of the College.
  - e. The individual must subscribe to the notion that the mission of education is second to no other priority.
  - f. The individual must adhere to the "Compartmentalization of Decision Authority" table and mitigate conflicts of interest.
3. External activities must not compromise an individual's ability to perform all the activities expected of him or her as an employee of CNU.
4. An individual may not receive remuneration for the conduct of his or her research or other California Northstate activity except through University channels (such as salary).
5. An individual may not conduct research or clinical activity at CNU or carry on other CNU activities under circumstances in which there exists an unmanaged conflict of interest.
6. CNU researchers may not be precluded from publishing their work by agreements with external sponsors or on account of the interest of an external organization in which a faculty mentor or supervisor has a financial interest.

7. CNU facilities, equipment, and personnel may be used only for CNU activities and purposes, except when the University specifically authorizes other uses.
8. An individual may not participate directly in the negotiation of research agreements, license agreements, equipment purchases or other arrangements between the University and an organization in which the individual has a significant financial interest.
9. Authors must fully disclose related significant financial interests and outside activities when submitting for publication (including articles, abstracts, manuscripts submitted for publication), in presentations at professional meetings, and in applications for funding.
10. In all scientific and scholarly publications and all manuscripts submitted for publication, authors must acknowledge the sources of support for all activities leading to and facilitating preparation of the publication or manuscript.
11. Participation by any individual responsible for the design, conduct or reporting of research involving human subjects and holding a related significant financial interest that may be affected by the research must receive especially rigorous review and must not compromise the objectivity of the research or the well-being of research subjects.
12. Research that is proposed to be sponsored by a privately held entity in which the faculty member who would conduct such research has an equity interest or Board seat or other significant financial interest (SFI) must be reviewed and approved in advance by the Office of the Vice President of Research (VPR) for conflict of interest evaluation.

#### c. Conflicts of Interest in Human Subjects Research

Conflicts of interest related to research involving human subjects pose special concerns. The University and its researchers have ethical obligations to honor the rights and protect the safety of persons who participate in research conducted at the University. SFIs held by those conducting the research may compromise the fulfillment of those ethical obligations and the well-being of the research subjects, as well as the integrity of the related research. Accordingly, a person with an unmanaged conflict of interest is prohibited from participating in the conduct of such research. In addition, research involving human subjects where there is a financial conflict of interest may only go forward if the design and circumstances of the human subjects research are such that they serve to protect both the human subjects and the objectivity of the data obtained. For example, research that includes multiple independent sites, or where the intervention or choice of device is blinded to the investigators, has an independent data and safety monitoring board, or has other such protective elements, may be allowed to proceed with an appropriate conflict of interest management plan. In order to address these special concerns, when human subjects are involved in the research, conflict of interest review will be coordinated with the appropriate CNU Institutional Review Board (IRB).

#### d. Start-up Companies

Individual relationships with "startup" ventures - relatively newly formed, privately held, for-profit companies that often may be based on intellectual property developed by the individual at California Northstate or elsewhere - present opportunities for development and commercialization of inventions, but may also create conflicts of interest and commitment. In particular, while close involvement of the individual is often critical to the further development of the technology, multiple relationships of the individual with the start-up venture magnify the concern regarding the individual's commitment to their University responsibilities.

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Generally, use of CNU space by a startup is not permitted, except when using CNU equipment or laboratories subject to a written agreement with the University, with strict limitations as to time and extent, and only after review and approval by the Office of VPR. For faculty members, the Faculty Handbook and other relevant policies govern the relationships. Policy guidelines specific to faculty relationships with such ventures appear as Appendix C to this general policy statement.

#### e. Significant Financial Interests

Income and other financial interests that are large compared to the individual's institutional salary pose a special challenge. They can create a perception that calls into question the individual's commitment and obligation to CNU. Some may find it difficult to believe that such high value interests do not compromise the individual's objectivity. And, indeed, high value financial interests do have the potential for greater bias, and are also inherently more difficult to manage. An Independent Committee on Conflicts of Interest (ICOCI) will be established to review the case of SFIs, and carefully consider the greater likelihood of conflict they represent.

In order to provide sufficient information to the ICOCI to enable it to determine whether actual undue bias exists and to recommend appropriate management schemes for relevant conflicts of interest, the independent ICOCI Committee will solicit additional detailed information from disclosers whose significant financial interests (excluding University compensation) exceed \$500 in the past twelve months and that are related to their institutional responsibilities. Such supplemental questions request more specificity on the total amounts received, the time that such financial interests demand, a detailed explanation of the relationship of the financial interest to an individual's research or, if the individual is in an academic leadership role, whether and how, the financial interests are related to the purpose of the unit for which the individual has administrative or academic responsibility.

Individuals or institutions receiving grant funds from the National Institute of Health or other governmental agencies shall be subject to the requirements of each agency, including the disclosure of Significant Financial Interests, which records shall be maintained by the University for a period of not shorter than three years. Failure by University personnel to disclose Financial Conflicts of Interest, or failure to maintain adequate records shall result in disciplinary measure for the employee, up to and including termination. Upon request by the granting agency, University agrees to provide a written certification that establishes University's willingness and ability to adhere to the Financial Conflict of Interest set forth by that agency. University agrees to provide an annual written report to granting agency of any actual financial conflicts of interest that may have arisen. Written report shall be due upon the end of the first fiscal quarter. University further agrees to publish on its website the Financial Conflict of Interest policy.

At the onset of the relationship with granting agency and before the receipt by University of any funds from granting agency, University shall provide a written report to the agency setting forth either the presence or absence of any significant conflicts of interest. Upon determination by the granting agency in conjunction with the University that a conflict exists, both agency and University agree to work collaboratively to resolve the conflict. University agrees to provide granting agency with a report of any significant financial conflicts of interest and work collaboratively with the granting agency to resolve any such conflicts. A Mitigation Report will also be submitted to granting agency once a bias is





discovered by University. University also agrees to notify the granting agency in writing if any bias arises or exists that could cause a potential conflict at the time University becomes aware of such potential conflict.

In the event a significant financial conflict of interest arises, University agrees to immediately notify the granting agency of the significant financial conflict of interest. This requirement shall be deemed complete upon University sending via certified mail a report setting forth the significant financial conflict of interest. University and granting agency shall work collaboratively to resolve the conflict and University shall submit a Mitigation Report to granting agency.

University has granted authority to each Principal Investigator to ensure the above policies and procedures are strictly adhered to.

## II. Procedures

### a. Disclosure

The responsibility for addressing conflict of interest rests, in the first instance, with the individual. An essential step is for the individual involved to make full disclosure of relevant information to the Conflicts of Interest Office. As described in greater detail below, certain individuals are required to make regular, annual disclosures, with updates as needed; others need only disclose on an ad hoc basis. When a disclosure is required, it will be reviewed by the Independent Committee on Conflicts of Interest (ICOCI), which will determine what should be done to avoid or manage any conflict of interest appropriately.

The confidentiality of the disclosures will be respected as far as possible. In particular, the information on the forms will not be shared except with authorized individuals in the conduct of their official University responsibilities.

#### i. Required Initial and Annual Disclosures

All faculty members with University appointments of greater than 50% time; all faculty who hold administrative positions; all faculty and staff who serve as members of a research reviewing committee (e.g., IRB, IACUC, Radiation Safety); and all faculty and staff who are responsible for the design, conduct or reporting of research are required to submit an annual external interest disclosure form describing their external activities and financial interests. The disclosures must be in writing, on the forms approved by the ICOCI, and must be submitted to the Conflicts of Interest Office within Human Resources Department.

Whenever an application for funding of any research project is submitted, each individual responsible for the design, conduct or reporting of the research is required to have an up-to-date disclosure on file with the Conflicts of Interest Office.

Any individual carrying out research or other activities supported by the federal Public Health Service (PHS) or supported by another sponsor that mandates compliance with the PHS regulations, must refer to and comply with Appendix A. Any individual carrying out research or other activities supported by the National Science Foundation (NSF) or other sponsor that mandates the NSF policy, must refer to and comply with Appendix B. Any individual that is not carrying out research or other

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activities supported by PHS or NSF must comply with the procedures as prescribed below in this general procedure.

All faculty, irrespective of funding support, that have relationships with startup companies must also comply with Appendix C. All faculty and full time non-faculty employees must also comply with the Policy and Procedure on Conflict of Commitment contained in Appendix D.

ii. **Material Change from Annual Disclosure**

Whenever SFIs or internal responsibilities change materially from those described in the annual disclosure, the disclosure should be submitted as soon as possible, but no later than 30 days after the individual's knowledge of such events.

iii. **Other required annual disclosures**

Certain senior administrators, with or without faculty appointments, designated by the President are also required to submit disclosures of outside activities and financial interests and thereafter annually submit disclosures of outside activities and financial interest for as long as the individual continues to be designated by the President as being required to submit such disclosures. These disclosures must be prepared on the Conflicts of Interest Disclosure Form and submitted to the Conflicts of Interest Office for review.

iv. **Ad hoc disclosures by those not required to file annual disclosures**

Postdoctoral appointees, non-faculty employees other than designated senior administrators, and students are not required to submit annual disclosure forms unless they are identified as being responsible for the design, conduct, or reporting of research. If there is any possibility of a conflict of interest with respect to an individual's non-research activities, the individual should consult with his or her supervisor, a senior administrator in the department, the Dean of the College, or the Conflicts of Interest Office.

b. **Review by the Independent Committee on Conflicts of Interest**

The ICOCI is composed of members with no financial relationship with the institution and are jointly appointed by the Human Resource Director, the President, and a member of the Board of Trustees.

ICOCI reviews disclosures submitted to the Conflicts of Interest Office to determine whether the Discloser's SFI(s) present(s) a conflict of interest with the Discloser's University responsibilities, and if so, by what means the conflict should be managed, reduced or eliminated. A conflict exists when a SFI could directly and significantly impact the individual's ability to carry out their University responsibilities without undue bias.

The Committee may delegate review of routine matters to one of its members or supporting staff. If necessary, the Committee may discuss disclosure-related matters with the individual involved and may also consult with others who may have relevant information. A Discloser is entitled to meet with the ICOCI.

The Committee will review any SFIs in the context of the individual's overall California Northstate responsibilities, i.e., academic, clinical or administrative (commonly referred to as an "Activities Review") and with respect to each research award on which the Discloser is identified

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as responsible for the design, conduct, or reporting of the research to determine if a SFI is related to the award and whether the SFI creates a conflict of interest related to that research award (commonly referred to as "Transactional Review").

#### c. Guidelines for Determining Conflicts of Interest on Research Awards

The Committee will determine whether a Discloser's SFI is related to the funded or proposed research and, if so, whether the SFI is a financial conflict of interest (FCOI). A Discloser's SFI is related to funded or proposed research when the Committee 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 Committee may consult with the Investigator in the determination of whether a SFI is related to the research.

A financial conflict of interest exists when the Committee reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the research.

Among the factors that should be taken into consideration in the determination of an FCOI include the role of the Discloser and the opportunity to bias the results, the nature of the research being proposed, whether the work is funded by an entity in which the Investigator holds a SFI, and consideration of the value of the SFI in relation to the size and value of the entity. The factors that should be considered include:

1. Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or
2. Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; or
3. Whether the goal of the research is to evaluate an invention linked to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention); or
4. Where the research involves human subjects whether there are double blind conditions or the involvement of a data and safety monitoring board; or
5. Where the SFI is in a privately held company, whether the researcher's SFI could result in the researcher having influence over company decisions, or whether the research could have a significant impact on the company's business or financial outlook (excluding Phase I SBIRs and STTRs); or
6. The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity); or
7. Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the Discloser's technology, the amount of commercialization payments received by the faculty member from that technology, both currently or in the future; or
8. The number and nature of relationships a Discloser has with an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts; or
9. Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI; or
10. Whether other scientific groups are independently pursuing similar questions; or
11. Whether sufficient external review of the research conducted and the reporting of research results exist to mitigate undue bias; or

12. Whether the goal of the project is a comparative evaluation of a technology in which the Discloser has a SFI; or
13. Whether the project involves a subaward to an entity in which the Discloser has a SFI.

#### d. Management of Significant Financial Interest that Pose a Conflict of Interest

If a conflict of interest exists, the Committee will determine by what means – such as the individual's recusal from decisions affecting the conflicting entity, abstention from the external activity, modification of the activity, and/or monitoring of the activity by a subcommittee -- the conflict should be avoided or managed in order to mitigate undue bias. In making those determinations, the ICOCI will be guided by the principles discussed in this Policy and in the Faculty Handbook, and may be informed by the deliberations of the relevant Institutional Review Board (IRB), as appropriate. The Committee will also take into consideration whether the Discloser's ongoing role is necessary to continue advancing the research, based upon the factors such as the uniqueness of his or her expertise and qualifications.

Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- Severance of relationships that create financial conflicts;
- For research projects involving human subjects research, use of a data and safety monitoring board;
- Double-blind conditions;
- Provisions to conduct the work simultaneously at multiple sites;
- Written disclosure of the conflict to all individuals working on the research project; and
- Annual reports on the research progress to the Committee.

If the Committee determines that a conflict exists, it will communicate this determination and the means it has identified for eliminating or managing the conflict, in writing, to the individual, to the relevant Principal Investigator in the case of sponsored research, and to the appropriate Dean and Department Chair where conflicts of interest arise with respect to teaching, clinical, or administrative responsibilities. The Committee will also communicate with the Office of VPR the fact that the disclosure has been reviewed and its summary determination, but not the substance of the disclosure. The Committee will keep a record of the disclosure and other relevant information for at least three years. If the Committee prescribes monitoring of the activity, it will describe what monitoring shall be performed and what records are to be kept.



If the individual is not satisfied with the decision of the Committee, he or she may request in writing to the Committee that the matter be referred to the Office of VPR for a decision. A written statement of the findings and recommendations of the Committee shall accompany any matter referred to the VPR, with copies to the individual, and the appropriate Dean and Department Chair. The VPR will notify the individual, the Committee, and the Dean and Department Chair of his or her decision after receiving the Committee's report. The VPR's decision will be final, and any failure by the individual to adhere to the decision will be cause for disciplinary action, including, in severe cases, termination.

#### e. Significant Financial Interest Relating to Specific Areas

Conflicts of interest procedures relating to certain specific areas are addressed in the following Appendices:

APPENDIX A - Conflict of Interest Procedures Applicable to Public Health Services Funding  
APPENDIX B - Conflict of Interest Procedures Applicable to National Science Foundation Funding  
APPENDIX C- Policy Applicable to Faculty with Relationships with Start-Up Companies  
APPENDIX D -Policy and Procedure on Conflict of Commitment

#### f. Compartmentalization of Decision Making Authority to Avoid Conflicts of Interest

Each individual with decision making authority within the College of Medicine must adhere to the "Compartmentalization of Decision Authority" table and mitigate conflicts of interest.

The table accompanies as follows:

APPENDIX E – Compartmentalization of Decision Authority Table

## APPENDIX A- Conflict of Interest Procedures Applicable to Public Health Services Funding

The federal Public Health Service (PHS) has adopted regulations (42 CFR Part 50 and 45 CFR Part 94) on *Promoting Objectivity in Research*. These regulations describe the actions an individual and the institution must take in order to promote objectivity in research. The regulations apply to all grants, cooperative agreements, and research contracts (but not Phase 1 Small Business Innovation Research or Small Business Technology Transfer program grants) funded by the PHS. The regulations require that applicants for PHS funding (e.g., funding from

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the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control, et al.), prior to application for PHS funds, disclose to the institution any significant financial interests related to their institutional responsibilities.

#### Definitions

Solely for those applying for or receiving funds from the PHS, *Institutional responsibilities* means an Investigator's professional activities on behalf of the Institution (e.g., teaching, administration, research or clinical care). Specifically, these include:

- Externally sponsored research or scholarly activities (includes activities such as proposing, conducting, and analyzing research and disseminating results);
- Departmental/University research (includes participation in study sections, peer review of manuscripts, or effort on non-sponsored research);
- Instruction/University Supported Academic activities (including preparation for and presentations of formal and informal courses to students/trainee groups, mentoring students and trainees, and participation in resident training);
- Clinical service activities such as performing services for the California Northstate Medical Group and affiliated hospitals;
- Administrative activities including serving as Department Chair, Program Director, or service on institutional committees, participation in department activities or faculty advisory boards, etc.; or
- Special Service activities on behalf of the University including institutional community service.

Institutional responsibilities do not include:

- Volunteer individual community or public service unrelated to one's responsibilities on behalf of the University; or
- Other activities over and above or separate from responsibilities in the primary position.

*Investigator* means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants. The Principal Investigator (Project Director), upon consideration of the individual's role and degree of independence in carrying out the work, will determine who is responsible for the design, conduct, or reporting of the research.

The definition of Significant Financial Interest set forth herein replaces II [E] of the general policy and procedure.

*Significant Financial Interest* means:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities (e.g., consulting and other outside compensated professional work including service on Scientific Advisory Boards or similar boards directly related to one's University research or scholarship; or service in external professional organizations and societies related to one's work):

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- i. 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. For purposes of this definition, 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;
- ii. With regard to any non-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, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- iii. With regard to intellectual property rights and interests (e.g., patents, copyrights), a significant financial interest exists upon receipt of income of greater than \$5,000 related to such rights and interests;
- iv. With respect to the Investigator only (but not the Investigator's spouse or dependent children), a significant financial interest exists if the Investigator is a member of the Board of Directors or serves as a fiduciary officer of any entity.

(2) Any reimbursed or sponsored travel (i.e., that which is reimbursed to or paid on behalf of the Investigator, the Investigator's spouse or dependent children), related to the Investigator's responsibilities, if the cost or value received from a single entity exceeds \$5,000 for the preceding twelve (12) months. This 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. The details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

(3) The term *significant financial interest* does not include the following types of financial interests:

- i. Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
- ii. 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;
- iii. 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
- iv. 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.





## **Disclosure**

Prior to the submission of an application for funding from a PHS agency, the Principal Investigator and all other Investigators must have disclosed to the Conflicts of Interest Office an up-to-date listing of their Significant Financial Interests [SFI] (and those of their spouse and dependent children), as defined above. Any new Investigator, who, subsequent to the submission of an application for funding from a PHS agency, or during the course of the research project, plans to participate in the project, must similarly disclose their SFI to the Conflicts of Interest Office promptly and prior to participation in the project.

Each Investigator who is participating in the PHS-funded research must submit an updated disclosure of SFI at least annually, during the period of the award. Such disclosure must include any information that was not disclosed initially to California Northstate, pursuant to this Policy, or in a subsequent disclosure of SFI (e.g., any financial conflict of interest [FCOI] identified on a PHS-funded project that was transferred from another Institution), and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

Each Investigator who is participating in the PHS-funded research must submit an updated disclosure of SFI within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

## **Review by the Independent Committee on Conflicts of Interest**

The Independent Committee on Conflict of Interest (ICOCI) will conduct reviews of disclosures submitted to the Conflicts of Interest Office. The Committee will review any SFI that has been identified in a disclosure; these interests will be compared to each PHS research award on which the Investigator is identified as responsible for the design, conduct, or reporting of the research to determine if a SFI is related to the award and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research award.

## **Guidelines for Determining "Relatedness" and Financial Conflict of Interest**

The Committee will determine whether an Investigator's SFI is related to the PHS-funded research and, if so, whether the SFI is a financial conflict of interest. An Investigator's SFI is related to PHS-funded research when the Committee reasonably determines that the SFI: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. The Committee may involve the Investigator in the determination of whether a SFI is related to the PHS-funded research.

A financial conflict of interest exists when the Committee reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

In determining if an Investigator's SFI is related to PHS-funded research, and if so, whether the relationship creates a FCOI, the Committee considers the role of the Investigator and the opportunity (if any), to bias the results, the nature of the research being proposed, and the value of the SFI in relation to the size and value of the entity. In addition, the Committee may also consider the following factors:

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1. Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or
2. Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; or
3. Whether the goal of the research is to evaluate an invention linked to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention); or
4. Where the research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board; or
5. Where the SFI is in a privately held company, whether the researcher's SFI could result in the researcher having influence over company decisions, or whether the research could have a significant impact on the company's business or financial outlook (excluding Phase I SBIRs and STTRs); or
6. The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity); or
7. Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the Investigator's technology, the amount of commercialization payments received by the faculty member from that technology, both currently or in the future; or
8. The number and nature of relationships an Investigator has with an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts; or
9. Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI; or
10. Whether other scientific groups are independently pursuing similar questions; or
11. Whether sufficient external review of the research conducted and the reporting of research results exist to mitigate undue bias; or
12. Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has a SFI; or
13. Whether the project involves a subaward to an entity in which the Discloser has a SFI.

### **Management of Significant Financial Interest that Pose Financial Conflicts of Interest**

If a conflict of interest exists, the Committee will determine by what means – such as the individual's recusal from decisions affecting the conflicting entity, abstention from the external activity, modification of the activity, and/or monitoring of the activity by a subcommittee–the conflict should be avoided or managed in order to mitigate undue bias. In making those determinations, the Committee will be guided by the principles discussed in this Policy and in the Faculty Handbook, and may be informed by the deliberations of the relevant Institutional Review Board (IRB), as appropriate. The Committee will also take into consideration whether the Investigator's ongoing role is necessary to continue advancing the research, based upon the factors such as the uniqueness of his or her expertise and qualifications.

Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- a. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research, to research personnel working on the study, to IRBs, IACUCs, etc.);
- b. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants;

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- c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- d. Modification of the research plan;
- e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- f. Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- g. Severance of relationships that create financial conflicts;
- h. For research projects involving human subjects research, use of a data and safety monitoring board;
- i. Double-blind conditions;
- j. Provisions to conduct the work simultaneously at multiple sites;
- k. Written disclosure of the conflict to all individuals working on the research project; and
- l. Annual reports on the research progress to the Committee.

If the Committee determines that a conflict exists, it will communicate its determination and the means it has identified for eliminating or managing the conflict, in writing, to the individual, to the relevant Principal Investigator (Project Director), and the appropriate dean or department chair. The Conflicts of Interest Office will keep a record of the disclosure and other relevant information for at least three years. If the Committee prescribes monitoring of the activity, it will describe what monitoring shall be performed and what records are to be kept.

If the individual is not satisfied with the decision of the Committee, he or she may request that the matter be referred to the Vice President of Research (VPR) for a decision. A written statement of the findings and recommendations of the Committee shall accompany any matter referred to the VPR, with copies to the individual, and the appropriate Dean or Department Chair. The VPR will notify the individual, the Committee, and the Dean or Department Chair of his or her decision after receiving the Committee's report. The VPR's decision will be final, and any failure by the individual to adhere to the decision may be cause for disciplinary action, including, in severe cases, termination.

No expenditures on PHS awards will be permitted until the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the Committee necessary to manage the Conflict of Interest. The Conflicts of Interest Office will communicate with the PHS Awarding Component to notify it of the existence and the nature of a Financial Conflict of Interest and whether the conflict has been managed, reduced, or eliminated.

The Conflicts of Interest Office will keep a record of Investigator disclosures of financial interests and the Committee's review of, and response to, such disclosure and all actions under this policy. Such records will be maintained and kept for three years from the date the final expenditures report is submitted for grants, for three years from the date of final payment for contracts, or, where applicable, for time periods as otherwise specified in relevant HHS Regulations.

#### **Public Accessibility to Information Related to Financial Conflicts of Interest**



Prior to the expenditure of any funds under a PHS-funded research project, California Northstate will ensure public accessibility, via a publicly accessible Web site or by written response to any requestor within five business days of a request, of information concerning any SFI disclosed that meets the following three criteria:

- i. The Significant Financial Interest was disclosed and is still held by the senior/key personnel. Senior/key personnel are the PD/PI and any other person identified as senior key personnel by the University in the grant application, progress report or any other report submitted to the PHS by the University;
- ii. California Northstate has determined that the Significant Financial Interest is related to the PHS- funded research; and
- iii. California Northstate has determined that the Significant Financial Interest is a Financial Conflict of Interest.

The information that California Northstate will make available via a publicly accessible Web site or in a written response to any requestor within five days of request will 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 Significant Financial Interest is held; (iv)The nature of the Significant Financial Interest; and
- iv. The approximate dollar value of the Significant Financial Interest in the following ranges: \$0-\$4,999; \$5,000-9,999; \$10,000- \$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

If California Northstate uses a publicly accessible Web site to comply with the public disclosure requirements of the PHS regulations, the information posted will be updated at least annually, and within sixty days of receipt or identification of information concerning any additional SFI of the senior/key personnel for the PHS-funded research project that had not been previously disclosed, or upon the disclosure of a SFI of senior/key personnel new to the PHS-funded research project, if it is determined by the Committee that the SFI is related to the PHS-funded research and is a Financial Conflict of Interest.

If California Northstate responds to written requests for the purposes of public accessibility, it will ascertain from the Investigator that the information provided is current as of the date of the correspondence, and will note in its written response that the information is subject to updates, on at least an annual basis and within 60 days of the California Northstate's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

Information concerning the SFI's of an individual, as limited by this Policy, will remain available, for responses to written requests or for posting via California Northstate's publicly accessible Web site for at least three years from the date that the information was most recently updated.

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### **Reporting of Financial Conflicts of Interest**

Prior to the expenditure of any funds under a PHS-funded research project, California Northstate will provide to the PHS Awarding Component an FCOI report compliant with PHS regulations regarding any Investigator's SFI found to be conflicting and will ensure that the Investigator has agreed to and implemented the corresponding management plan. While the award is ongoing (including any extensions with or without funds), California Northstate will provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes in the management plan.

For any SFI that is identified as conflicting subsequent to an 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), California Northstate will provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that California Northstate has implemented a management plan and the Investigator has agreed to the relevant management plan.

### **Training Requirements**

Each Investigator must complete training on *The California Northstate Conflict of Interest Policy Applicable to Public Health Service Funding*. For PHS Investigators, California Northstate has imbedded training on conflict of interest into its annual disclosure form. Each Investigator must complete the disclosure form prior to engaging in research related to any PHS-funded grant, and immediately (as defined below) when any of the following circumstances apply:

1. California Northstate revises this Policy, or procedures related to this Policy, in any manner that affects the requirements of Investigators (training will be completed in the manner and within the time frame specified in communications announcing such changes)
2. An Investigator is new to California Northstate (training must be completed through completion of the disclosure form within 30 days of joining California Northstate); or
3. California Northstate finds that an Investigator is not in compliance with this Appendix to California Northstate's Conflict of Interest Policy or a management plan issued under this Appendix (training must be completed within 30 days in the manner specified by the COIC).

### **Subrecipient Requirements**

California Northstate shall as part of a written subrecipient agreement with a subrecipient under a PHS prime award, establish whether the financial conflicts of interest policy of California Northstate or that of the subrecipient will apply to the subrecipient's investigator(s). If the subrecipient relies on its conflicts of interest policy, the subrecipient shall certify as part of the subrecipient agreement, that its policy complies with 42 CFR Part 50 and 45 CFR Part 94, as appropriate. In either case, the subrecipient agreement will include time periods to meet the disclosure and/or Financial Conflict of Interest reporting requirements of California Northstate to PHS.

### **Failure to Comply with California Northstate's Conflict of Interest Policy Applicable to Public Health Service Funding**

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Whenever an FOIC is not identified or managed in a timely manner, including, for example, because the underlying Significant Financial Interest is not disclosed timely by an Investigator or, because an FCOI was not timely reviewed or reported by a sub-recipient or by California Northstate); or because an investigator failed to comply with a management plan; then California Northstate will complete a retrospective review within 120 days of determining noncompliance to determine whether any PHS-funded research, or portion thereof, conducted during the period of noncompliance was biased in the design, conduct, or reporting of such research. The VPR will appoint one or more individuals to determine if the research was biased. If bias is found, California Northstate will develop and implement a plan to mitigate the bias. California Northstate will notify the PHS Awarding Component promptly and will submit a mitigation report to the PHS Awarding Component within 120 days of the determination of noncompliance.

No expenditures of funds on PHS awards will be permitted unless the Investigator has complied with the Disclosure requirements of this Appendix and has agreed, in writing, to comply with any Committee-approved FCOI management plan.

In any case in which the Department of Health and Human Services 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 financial conflict of interest that was not managed or reported by the Institution as required by the PHS regulations, California Northstate will require the Investigator involved to disclose the financial conflict of interest in each public presentation of the research and to request an addendum to previously published presentations.

Any failure by an individual to adhere to this Policy may be cause for disciplinary action, including, in severe cases, termination.

## APPENDIX B- Conflict of Interest Procedures Applicable to National Science Foundation Funding

The National Science Foundation (NSF) requires each grantee institution employing more than fifty persons to maintain an appropriate written and enforced policy on conflict of interest and that all conflicts of interest for each award be managed, reduced or eliminated prior to the expenditure of the award funds. Therefore, for every NSF application for funding, each Investigator must disclose to the Conflicts of Interest Office all significant financial interests of the Investigator (including those of the investigator's spouse and dependent children):

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- i. That would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or
- ii. In entities whose financial interests would reasonably appear to be affected by such activities.

### Definitions

The term "**Investigator**" means the principal investigator, co-principal investigators, and any other person at the institution who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF.

For those applying for or receiving funds from the NSF, the definition of Significant Financial Interest described herein replaces II[E] of the general policy and procedure. The term "**significant financial interest**" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). With respect to the Investigator only (and not the investigator's spouse and dependent children), a *significant financial interest* exists if the Investigator is a member of the Board of Directors of any entity, or serves as a fiduciary officer of such an entity.

The term does not include:

- i. Salary, royalties or other remuneration from the applicant institution;
- ii. Any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program;
- iii. Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- iv. Income from service on advisory committees or review panels for public or nonprofit entities;
- v. An equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity; or
- vi. Salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$10,000 during the twelve month period.

### Disclosure

All Investigators must have a current financial disclosure on file with the University's Conflict of Interest Office at the time the proposal is submitted to NSF. Financial disclosures must be updated during the period of the award, either on an annual basis, or as new reportable significant financial interests are obtained.

### Review by the Independent Committee on Conflict of Interest

The Independent Committee on Conflicts of Interest (ICOCI) will review financial disclosures, determine whether a conflict of interest exists, and determine what conditions or restrictions, if any, should be imposed to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the Committee reasonably determines that a significant financial interest

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could directly and significantly affect the design, conduct, or reporting of NSF-funded research or educational activities.

### **Guidelines for Determining Conflict of Interest**

The Committee will determine whether an Investigator's SFI is related to the NSF-funded research and, if so, whether the SFI is a financial conflict of interest. An Investigator's SFI is related to NSF-funded research when the Committee reasonably determines that the SFI: could be affected by the NSF-funded research; or is in an entity whose financial interest could be affected by the research. The Committee may involve the Investigator in the determination of whether a SFI is related to the NSF-funded research or educational activity.

A financial conflict of interest exists when the Committee reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the NSF-funded research or educational activity.

Factors that may be taken into consideration in this determination include the role of the Investigator and the opportunity to bias the results, the nature of the research being proposed, and consideration of the value of the SFI in relation to the size and value of the entity. Other factors that might be considered include:

1. Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or
2. Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; or
3. Whether the goal of the research is to evaluate an invention linked to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention); or
4. Where the research involves human subjects whether there are double blind conditions or the involvement of a data and safety monitoring board; or
5. Where the SFI is in a privately held company, whether the researcher's SFI could result in the researcher having influence over company decisions, or whether the research could have a significant impact on the company's business or financial outlook (excluding Phase I SBIRs and STTRs); or
6. The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity); or
7. Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the Discloser's technology, the amount of commercialization payments received by the faculty member from that technology, both currently or in the future; or
8. The number and nature of relationships a Discloser has with an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts; or
9. Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI; or
10. Whether other scientific groups are independently pursuing similar questions; or
11. Whether sufficient external review of the research conducted and the reporting of research results exist to mitigate undue bias; or
12. Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has a SFI; or
13. Whether the project involves a subaward to an entity in which the Discloser has a SFI.

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### **Management of Significant Financial Interest that Pose Financial Conflicts of Interest**

If a conflict of interest exists, the Committee will determine by what means – such as the individual's recusal from decisions affecting the conflicting entity, abstention from the external activity, modification of the activity, and/or monitoring of the activity by a subcommittee-- the conflict should be avoided or managed in order to mitigate undue bias. In making those determinations, the Committee will be guided by the principles discussed in this Policy and in the Faculty Handbook, and may be informed by the deliberations of the relevant Institutional Review Board (IRB), as appropriate.

Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- a. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- b. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants;
- c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- d. Modification of the research plan;
- e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- f. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- g. Severance of relationships that create financial conflicts;
- h. For research projects involving human subjects research, use of a data and safety monitoring board;
- i. Double-blind conditions;
- j. Work being conducted simultaneously at multiple sites;
- k. Written disclosure of the conflict to all individuals working on the research project; and
- l. Annual reports on the research progress to the Committee.

If the Committee determines that a conflict exists, it will communicate its determination and the means it has identified for eliminating or managing the conflict, in writing, to the individual, to the relevant Principal Investigator (Project Director), and the appropriate dean or department chair. The COI Office will keep a record of the disclosure and other relevant information for at least three years. If the Committee prescribes monitoring of the activity, it will describe what monitoring shall be performed and what records are to be kept.

If the individual is not satisfied with the decision of the Committee, he or she may request that the matter be referred to the Vice-President of Research (VPR) for a decision. A written statement of the findings and recommendations of the Committee shall accompany any matter referred to the VPR, with copies to the individual, and the appropriate Dean and Department Chair. The VPR will notify the individual, the Committee, and the Dean and Department Chair of his or her decision after receiving the Committee's report.

Any failure by an individual to adhere to this Policy may be cause for disciplinary action, including, in severe cases, termination.

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No expenditures of funds on NSF awards will be permitted unless the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the Committee necessary to manage the Conflict of Interest.

California Northstate will keep NSF's Office of the General Counsel appropriately informed if it finds that it is unable to satisfactorily manage a conflict of interest.

## APPENDIX C -Policy Applicable to Faculty with Relationships with Start-Up Companies

One important aspect of the University's research endeavors is to enable the dissemination of research and new technologies to the benefit of society. Licensing activities and the start-up of new companies to further develop new technologies are important means of accomplishing this goal. Faculty relationships with "startup" ventures -relatively newly formed, privately held, for-profit companies that often are based on intellectual property developed by the faculty member at California Northstate or elsewhere -- present opportunities for development and commercialization of inventions but may also create conflicts of interest and commitment. In particular, while close involvement of the faculty member is often critical to the further development of the technology,

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multiple relationships of the faculty member with the start-up venture magnify the concern regarding the faculty member's commitment to their University responsibilities. This Policy, the Faculty Handbook and other relevant policies govern the following relationships.

1. ***Equity interests***• Faculty may hold equity interests in startups that license intellectual property developed either at California Northstate or at other entities. Such equity ownership must be promptly disclosed (i.e., within 30 days) to the COI Office on the prescribed form. Faculty accepting equity in such ventures should recognize that their ability to conduct research sponsored by that venture - especially research involving human subjects -may be restricted because of the conflict created by their ownership interest in the sponsoring entity. Therefore California Northstate faculty should consult with the Independent Committee on Conflicts of Interest (ICOCI) prior to accepting either an equity interest or financial sponsorship of research by the entity.
2. ***Membership on Board(s) of Directors***. Faculty may be permitted to serve on the Board of Directors of a startup (or, as the Faculty Handbook provides, of any company). In accordance with the policy stated in the Faculty Handbook with respect to all for-profit companies, the prospect of Board membership must be disclosed in advance to the Conflicts of Interest Office, and a Board seat may be accepted only with permission of the Committee, because of the fiduciary obligation that the seat creates and its potential for conflict with the faculty member's California Northstate duties and obligations. A faculty member who has personally assumed a Board seat should recognize that his or her ability to conduct research at California Northstate that is sponsored by the venture - especially research involving human subjects - **may be** restricted because of the conflict created by the fiduciary relationship with the venture. Faculty members who assume Board seats on startups should also be sensitive to the need to recuse themselves from all Board decisions that involve the University.
3. ***Service as an Operating Officer***. A full-time faculty member may not serve as an operating officer of a startup (or, as the Faculty Handbook provides, of any company) while not on leave. If a faculty member believes it is essential for the success of the venture to serve as an operating officer, he or she should request a full or partial leave from the Human Resources Director for a specified period of time, consistent with policies on leave in the Faculty Handbook. Such a leave would be without compensation by the University.
4. ***Student employment by a Startup***. Except in special and unusual circumstances, students under a faculty member's direction, paid for by a faculty member's grant, or in a faculty member's research group, may not be employed part- or full-time by a startup in which the faculty member has an SFI. Such special circumstances might exist, for example, where the student sought summer employment with the startup and planned to work in a field unrelated to his or her academic program. These circumstances must be approved in advance by the Vice-President of Research (VPR).
5. ***Employment of postdoctoral fellows and associates by a startup***. Postdoctoral fellows and associates under a faculty member's direction, paid for by a faculty member's grant, or in a faculty member's research group, should not be employed by a startup in which the faculty member has an SFI, to conduct research that overlaps with the fellow's university



research or is to be conducted on University premises. The VPR must approve in advance any proposed employment of a post-doctoral fellow or associate by a startup.

6. ***Use of California Northstate space.*** Use of California Northstate space by a startup is not permitted, except as provided in the next paragraph.
7. ***Use of California Northstate equipment or laboratory training.*** A startup may use California Northstate equipment or laboratories only subject to a written agreement with the University, and with strict limitations as to time and extent and only after review and approval by the VPR.

## APPENDIX D - Policy and Procedure on Conflict of Commitment

### A. Policy

The responsibility for addressing conflict of commitment rests, in the first instance, with the individual. An essential step is for the individual involved to make full disclosure of relevant information to the Conflicts of Interest Office. A conflict of commitment occurs when the commitment to external activities of a faculty or staff member adversely affects his or her capacity to meet University responsibilities. This form of conflict is easily defined and recognized since it

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involves a perceptible reduction of the individual's time and energy devoted to University activities.

California Northstate's Faculty Handbook provides guidance about the amount of time that may be given by faculty members to outside activities; it stipulates, for example, that a faculty member may not accept salaried employment at another institution while a full-time employee of California Northstate, that faculty may not spend more than one day in a seven-day work week on consulting activities, and that faculty ownership or management of private enterprises is subject to review and approval by the President and subject to limitations. It is important to recognize, however, that the obligations of California Northstate faculty move beyond the letter of these obligations to their spirit. The University requires that its faculty will meet their class schedules, but it also expects that they will be available to students outside of the classroom, will carry their share of committee responsibilities, will remain productively involved in their research and other scholarly pursuits, and, where applicable, will meet their clinical obligations. External activities that compromise or diminish a faculty member's capacity to meet these obligations represent a conflict of commitment. Deans and Department Chairs are responsible for ensuring that faculty meet their University obligations.

Full-time non-faculty employees are expected to satisfy all of the requirements of their jobs, and should not permit outside activities to interfere with the performance of their California Northstate obligations. Some departments prohibit staff employees from consulting or engaging in other outside employment because of the likelihood of such interference. Other departments may permit certain outside activities, with appropriate notice to and written approval by the employee's supervisor, so long as they do not interfere with employees' California Northstate obligations.

## **B. Procedure**

All faculty members with University appointments of greater than 50% time and all faculty members who hold administrative positions must make full disclosure of their external activities to the Conflicts of Interest Office. The Conflicts of Interest Office will prepare a summary report of an individual's external activities from the disclosure. This report will be provided to the relevant Dean or Chair for a determination of whether a conflict of commitment exists. If such a conflict exists, the Dean or Chair will discuss with the individual steps to be taken to resolve the matter. The Dean or Chair may consult with the President's Office as appropriate.





## APPENDIX E - Compartmentalization of Decision Authority Table

### Compartmentalization of Decision Authority to Prevent Direct Conflict of Interest

| Category of decision authority   | Board of Trustees | University President | University Vice President | Dean | Senior Associate Dean of Medical Education | Senior Associate Dean of Clinical Medicine | Other Deans/Chairs | Clinical Governance Committee | Faculty Committees | Faculty | Board of Directors |
|--|-------------------|----------------------|---------------------------|------|--|--|--------------------|-------------------------------|--------------------|---------|--------------------|
| <b>A = Approval</b> (integral position authority)  |                   |                      |                           |      |  |  |                    |                               |                    |         |                    |
| <b>AO = Approval on the Authority of Board of Trustees</b>   |                   |                      |                           |      |  |  |                    |                               |                    |         |                    |
| <b>I = In-charge</b> (execution, implementation, maintaining, monitoring, if more than one entities designated, then all designated entities have shared responsibility), and accountable to the Dean of College of Medicine.  |                   |                      |                           |      |  |  |                    |                               |                    |         |                    |
| <b>R = Recommendation</b> (proposing via committee action, advocacy, or supporting after review)   |                   |                      |                           |      |  |  |                    |                               |                    |         |                    |
| <b>Standard 1: Mission, Planning, Organization, and Integrity</b>  |                   |                      |                           |      |  |  |                    |                               |                    |         |                    |
| 1.1 Strategic Planning and Continuous Quality Improvement  | A                 | R                    |                           | R    | I  |  |                    | I                             | I                  | R       |                    |
| 1.2 Conflict of Interest Policies  | A                 | R                    |                           | R    |  |  |                    |                               |                    |         |                    |
| 1.3 Mechanisms for Faculty Participation in decision making  | A                 |                      |                           | R    |  |  | R                  |                               |                    |         |                    |
| 1.4 Affiliation Agreements-medical education is under the control of the faculty   | A                 |                      |                           | I    |  | R  |                    |                               |                    |         |                    |
| 1.5 Bylaws- describe the responsibilities and privileges of its administrative officers, faculty, medical students, and committees.  | A                 | R                    |                           | R    |  |  | R                  |                               |                    |         |                    |
| 1.6 Eligibility Requirements: all eligibility requirements of the LCME for initial and continuing accreditation  |                   |                      |                           | I    |  |  | R                  |                               |                    |         |                    |
| <b>Standard 2: Leadership and Administration</b>   |                   |                      |                           |      |  |  |                    |                               |                    |         |                    |
| 2.1 Administrative Officer and Faculty Appointments  |                   | OA                   |                           | I,R  |  |  |                    |                               | R                  |         |                    |
| 2.2 Dean's Qualifications- hired by the President on authority of BOT  | A                 | R                    |                           |      |  |  |                    | R                             | R                  |         |                    |
| 2.3 Access and Authority of the Dean to President  |                   |                      |                           | Yes  |  |  |                    |                               |                    |         |                    |
| 2.4 Sufficiency of Administrative Staff a sufficient number of associate or assistant deans, leaders of organizational units, and senior administrative staff  |                   |                      |                           | I    |  |  |                    |                               |                    |         |                    |
| 2.5 Responsibility of and to the Dean The principal academic officer at each campus is administratively responsible to the dean  |                   |                      |                           | I    |  |  |                    |                               |                    |         |                    |
| 2.6 Functional Integration of the Faculty the faculty at the departmental and medical school levels at each campus are functionally integrated by appropriate administrative mechanisms  |                   |                      |                           | A    | I  | I  | I                  | R                             |                    |         |                    |
| <b>Standard 3: Academic and Learning Environments</b>  |                   |                      |                           |      |  |  |                    |                               |                    |         |                    |
| 3.1 Resident Participation in Medical Student Education  |                   |                      |                           | I    |  |  |                    |                               |                    |         |                    |
| 3.2 Community of Scholars/Research Opportunities provides sufficient opportunities, encouragement, and support for medical student participation in research and other scholarly activities of its faculty.  |                   |                      |                           | I    | I  |  | A                  |                               |                    | R       |                    |
| 3.3 Diversity/Pipeline Programs and Partnerships- These activities include the use of programs and/or partnerships aimed at achieving diversity among qualified applicants for medical school admission and the evaluation of program  | A                 |                      |                           | OA   |  |  |                    |                               | I                  |         |                    |
| 3.4 Anti-Discrimination Policy- does not discriminate on the basis of age, creed, gender identity, national origin, race, sex, or sexual orientation.  | A                 |                      | I                         | R    |  |  |                    | R                             | R                  |         |                    |
| 3.5 Learning Environment/Professionalism The medical school and its clinical affiliates the ongoing development of explicit and appropriate professional behaviors in its medical students, faculty, and staff at all locations, share the responsibility for periodic evaluation, identify and promptly correct violations of professional standards.                     |                   |                      |                           | A    |  |  |                    | I                             | I                  | R       |                    |
| 3.6 Student Mistreatment- defines and publicizes its code of professional conduct for faculty-student relationships in its medical education program, develops effective written policies that address violations of the code; has effective mechanisms in place for a prompt response to any complaints; Mechanisms for reporting violations without fear of retaliation. |                   | OA                   |                           | I    | R  | R  | I                  | R                             | R                  |         |                    |
| <b>Standard 4: Faculty Preparation, Productivity, Participation, and Policies</b>  |                   |                      |                           |      |  |  |                    |                               |                    |         |                    |
| 4.1 Sufficiency of Faculty   |                   |                      |                           | A    | R  | R  | R                  | I                             | R                  |         |                    |



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| 4.2 Scholarly Productivity  |                   |                      |                           | A    | R  | R  | I                  | R                             | R                  |         |                    |
| 4.3 Faculty Appointment Policies- A medical school has clear policies and procedures in place for faculty appointment, renewal of appointment, promotion, granting of tenure, remediation, and dismissal that involve the faculty, the appropriate department heads, and the dean   | A                 | AO                   |                           | I, R |  | R  |                    |                               | R                  |         |                    |
| 4.4 Feedback to Faculty   |                   |                      |                           | A    | R  | R  | I                  | R                             | R                  |         |                    |
| 4.5 Faculty Professional Development  |                   |                      |                           |      |  |  | A, I               | R                             | R                  |         |                    |
| 4.6 Faculty/Dean Responsibility for Educational Program Policies- the dean and a committee of the faculty determine programmatic policies.  |                   |                      |                           | A    | I  |  | R                  | R                             | R                  | R       |                    |
| <b>Standard 5: Educational Resources and Infrastructure</b>   |                   |                      |                           |      |  |  |                    |                               |                    |         |                    |
| 5.1 Adequacy of Financial Resources- are derived from diverse sources and are adequate to sustain a sound program of medical education and to accomplish other programmatic and institutional goals.  | A                 | R                    |                           | I    | R  |  |                    | R                             | R                  | R       | A                  |
| 5.2 Dean's Authority/Resources for Curriculum Management- The Dean has sufficient resources and budgetary authority to fulfill his or her responsibility for the management and evaluation of the medical curriculum.   |                   |                      |                           | A, I | I  |  |                    | R                             | R                  |         |                    |
| 5.3 Pressures for Self-Financing- A medical school admits only as many qualified applicants as its total resources can accommodate and does not permit financial or other influences to compromise the school's educational mission.  |                   |                      |                           | A, I |  |  |                    | R                             | R                  |         |                    |
| 5.4 Sufficiency of Buildings and Equipment A medical school has, or is assured the use of, buildings and equipment sufficient to achieve its educational, clinical, and research missions.  |                   |                      | A                         | I, R |  |  |                    | R                             | R                  | R       |                    |
| 5.5 Resources for Clinical Instruction- A medical school has, or is assured the use of, appropriate resources for the clinical instruction of its medical students in ambulatory and inpatient settings and has adequate numbers and types of patients (e.g., acuity, case mix, age, gender)  |                   |                      |                           | A    | I  | I  |                    | R                             | R                  | R       |                    |
| 5.6 Clinical Instructional Facilities/Information Resources- has sufficient information resources and instructional facilities for medical student education.   |                   |                      |                           | A    | I  | I  |                    | R                             | R                  | R       |                    |
| 5.7 Security, Student Safety, and Disaster Preparedness- COM ensures that adequate security systems are in place at all locations and publishes policies and procedures to ensure student safety and to address emergency and disaster preparedness.  |                   | OA                   | I                         | R    |  |  |                    | R                             |                    | R       |                    |
| 5.8 Library Resources/Staff- supervised by a professional staff that is familiar with regional and national information resources and data systems and is responsive to the needs   |                   |                      | I                         | A    |  |  |                    |                               |                    | R       | R                  |
| 5.9 Information Technology Resources/Staff- well-maintained information technology resources sufficient in scope to support its educational and other missions.   |                   |                      | I                         |      | A  |  |                    |                               |                    | R       | R                  |
| 5.10 Resources Used By Transfer/Visiting Students- do not significantly diminish the resources available to already enrolled medical students.  |                   |                      |                           | A    |  |  | I                  |                               |                    | R       |                    |
| 5.11 Study/Lounge/Storage Space/Call Rooms- ensures that its medical students have, at each campus and affiliated clinical site, adequate study space, lounge areas, personal lockers or other secure storage facilities, and secure call rooms if students are required to participate in late night or overnight clinical learning experiences. |                   |                      | I                         | A    |  |  |                    |                               |                    | R       |                    |
| 5.12 Required Notifications to the LCME- notifies the LCME of any substantial change in the number of enrolled medical students; of any decrease in the resources available to the institution for its medical education program,   |                   |                      |                           | I, A | R  | R  |                    | R                             | R                  | R       |                    |



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| including faculty, physical facilities, or finances; of its plans for any major modification of its medical curriculum; and/or of anticipated changes in the affiliation status of the program's clinical facilities. The program also provides prior notification to the LCME if it plans to increase entering medical student enrollment on the main campus and/or in one or more existing geographically distributed campuses above the threshold of 10 percent, or 15 medical students in one year or 20 percent in three years; or to start a new or to expand an existing geographically distributed campus; or to initiate a new medical education track. |  |  |  |  |   |   |   |   |   |   |   |
| <b>Standard 6: Competencies, Curricular Objectives, and Curricular Design-</b>   |  |  |  |  |   |   |   |   |   |   |   |
| 6.1 Format/Dissemination of Medical Education Program Objectives and Learning Objectives- The faculty of a medical school define its medical education program objectives in outcome- based terms that allow the assessment of medical students' progress in developing the competencies that the profession and the public expect of a physician.   |  |  |  |  | A | R | R | R | I | R |   |
| 6.2 Required Clinical Experiences- The faculty of a medical school define the types of patients and clinical conditions that medical students are required to encounter, the skills to be performed by medical students, the appropriate clinical settings for these experiences, and the expected levels of medical student responsibility.   |  |  |  |  | A | R | R | R | I | R |   |
| 6.3 Self-Directed and Life-Long Learning-ensure that the medical curriculum includes self-directed learning experiences and time.  |  |  |  |  | A |   |   |   | I | R |   |
| 6.4 Inpatient/Outpatient Experiences- The faculty of a medical school ensure that the medical curriculum includes clinical experiences in both outpatient and inpatient settings.  |  |  |  |  | A |   | I |   | R |   |   |
| 6.5 Elective Opportunities- The faculty of a medical school ensure that the medical curriculum includes elective opportunities that supplement required learning experiences and that permit medical students to gain exposure to and deepen their understanding of medical specialties reflecting their career interests and to pursue their individual academic interests.   |  |  |  |  | A |   | I |   | R |   |   |
| 6.6 Service-Learning- The faculty of a medical school ensure that the medical education program provides sufficient opportunities for, encourages, and supports medical student participation in service-learning and community service activities.  |  |  |  |  | A |   |   | I |   |   |   |
| 6.7 Academic Environments- The faculty of a medical school ensure that medical students have opportunities to learn in academic environments that permit interaction with students enrolled in other health professions, graduate,   |  |  |  |  | A |   |   |   | R | I |   |
| 6.8 Education Program Duration- A medical education program includes at least 130 weeks of instruction.  |  |  |  |  | A | R | R | R | R | I | R |
| <b>Standard 7: Curricular Content</b>  |  |  |  |  |   |   |   |   |   |   |   |
| 7.1 Biomedical, Behavioral, Social Sciences- faculty ensure that the medical curriculum includes content from the biomedical, behavioral, and socioeconomic sciences to support medical students' mastery of contemporary scientific knowledge and concepts and the methods fundamental to applying them to the health of individuals and populations.   |  |  |  |  | A | R |   |   | R | I | R |
| 7.2 Organ Systems /Life Cycle /Primary Care /Prevention /Wellness /Symptoms / Signs /Differential Diagnosis, Treatment Planning, Impact of Behavioral/Social Factors- The faculty of a medical school ensure that the medical curriculum includes content and clinical experiences   |  |  |  |  | A | R |   |   | R | I | R |





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| 7.3 Scientific Method/Clinical/Translational Research- The faculty of a medical school ensure that the medical curriculum includes instruction in the scientific method and in the basic scientific and ethical principles of clinical and translational research.   |  |  |  |   |   |   | I,A |   | R | R |  |
| 7.4 Critical Judgment/Problem-Solving Skills- The faculty of a medical school ensure that the medical curriculum incorporates the fundamental principles of medicine, provides opportunities for medical students to acquire skills of critical judgment based on evidence and experience, and develops medical students' ability to use those principles and skills effectively in solving problems of health and disease.  |  |  |  | A | R | R |     | R | I | R |  |
| 7.5 Societal Problems- The faculty of a medical school ensure that the medical curriculum includes instruction in the diagnosis, prevention, appropriate reporting, and treatment of the medical consequences of common societal problems.   |  |  |  | A | R | R |     | R | I | R |  |
| 7.6 Cultural Competence/Health Care Disparities/Personal Bias- The faculty of a medical school ensure that the medical curriculum provides opportunities for medical students to learn to recognize and appropriately address gender and cultural biases in themselves, in others, and in the health care delivery process.  |  |  |  | A | R | R |     | R | I | R |  |
| 7.7 Medical Ethics- The faculty of a medical school ensure that the medical curriculum includes instruction for medical students in medical ethics and human values both prior to and during their participation in patient care activities and requires its medical students to behave ethically in caring for patients and in relating to patients' families and others involved in patient care.  |  |  |  | A | R | R |     | R | I | R |  |
| 7.8 Communication Skills- The faculty of a medical school ensure that the medical curriculum includes specific instruction in communication skills as they relate to communication with patients and their families, colleagues, and other health professionals.   |  |  |  | A | R | R |     | R | I | R |  |
| 7.9 Interprofessional Collaborative Skills- The faculty of a medical school ensure that the core curriculum of the medical education program prepares medical students to function collaboratively on health care teams that include health professionals from other disciplines as they provide coordinated services to patients. These curricular experiences include practitioners and/or students from the other health professions.   |  |  |  | A | R | R |     | R | I | R |  |
| <b>Standard 8: Curricular Management, Evaluation, and Enhancement</b>  |  |  |  |   |   |   |     |   |   |   |  |
| 8.1 Curricular Management- A medical school has in place an institutional body (e.g., a faculty committee) that oversees the medical education program as a whole and has responsibility for the overall design, management, integration, evaluation, and enhancement of a coherent and coordinated medical curriculum.  |  |  |  |   | A | R | R   | R | I | R |  |
| 8.2 Use of Medical Educational Program Objectives- The faculty of a medical school, through the faculty committee responsible for the medical curriculum, ensure that the medical curriculum uses formally adopted medical education program objectives to guide the selection of curriculum content, to review and revise the curriculum, and to establish the basis for evaluating programmatic effectiveness. The learning objectives of each required course and clerkship are linked to medical education program objectives. |  |  |  |   | A | R | R   | R | I | R |  |
| 8.3 Curricular Design, Review, Revision/Content Monitoring- The faculty of a medical school are responsible for the detailed development, design, and implementation of all components of the medical education program  |  |  |  | A | R | R | R   | R | I | R |  |
| 8.4 Program Evaluation- A medical school collects and uses a variety of outcome data, including national norms of accomplishment, to demonstrate the extent to which medical students are achieving medical education program objectives   |  |  |  | A | R | R | R   | R | I | R |  |



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| and to enhance medical education program quality. These data are collected during program enrollment and after program completion.   |  |    |  |   |   |   |   |   |   |   |  |
| 8.5 Use of Student Evaluation Data in Program Improvement- a medical school has formal processes in place to collect and consider medical student evaluations of their courses, clerkships, and teachers, and other relevant information.  |  |    |  | A | R | R | R | R | I | R |  |
| 8.6 Monitoring Of Completion of Required Clinical Experiences- A medical school has in place a system with central oversight that monitors and ensures completion by all medical students of required clinical experiences in the medical education program and remedies any identified gaps.  |  |    |  | A | I | I | R | R | R | R |  |
| 8.8 Monitoring Student Workload- faculty committee responsible for the medical curriculum and the program's administration and leadership ensure the development and implementation of effective policies and procedures regarding the amount of time medical students spend in required activities, including the total number of hours medical students are required to spend in clinical and educational activities during clerkships.  |  |    |  | A | R | R | I | R | R | R |  |
| <b>Standard 9: Teaching, Supervision, Assessment, and Student and Patient Safety</b>   |  |    |  |   |   |   |   |   |   |   |  |
| 9.1 Preparation of Resident and Non-Faculty Instructors- In a medical school, residents, graduate students, postdoctoral fellows, and other non-faculty instructors in the medical education program who supervise or teach medical students are familiar with the learning objectives of the course or clerkship and are prepared for their roles in teaching and assessment. The medical school provides resources to enhance residents' and non-faculty instructors' teaching and assessment skills, with central monitoring of their participation in those opportunities provided.  |  |    |  | A |   |   | I | R |   |   |  |
| 9.2 Faculty Appointments- A medical school ensures that supervision of medical student learning experiences is provided throughout required clerkships by members of the school's faculty.   |  | OA |  | I |   |   |   | R | R | R |  |
| 9.3 Clinical Supervision of Medical Students- A medical school ensures that medical students in clinical learning situations involving patient care are appropriately supervised at all times in order to ensure patient and student safety, that the level of responsibility delegated to the student is appropriate to his or her level of training, and that the activities supervised are within the scope of practice of the supervising health professional.   |  |    |  | A |   | I | I | R | R | R |  |
| 9.4 Variety of Measures of Student Achievement / Direct Observation of Core Clinical Skills- A medical school ensures- A medical school ensures that, throughout its medical education program, there is a centralized system in place that employs a variety of measures (including direct observation) for the assessment of student achievement, including students' acquisition of the knowledge, core clinical skills (e.g., medical history-taking, physical examination), behaviors, and attitudes specified in medical education program objectives, and that ensures that all medical students achieve the same medical education program objectives. |  |    |  | A | R | R | I | R | R | R |  |
| 9.5 Narrative Assessment- A medical school ensures that a narrative description of a medical student's performance, including his or her non-cognitive achievement, is included as a component of the assessment in each required course and clerkship of the medical education program whenever teacher-student interaction permits this form of assessment.  |  |    |  | A | R | R | I |   | R | R |  |



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| <b>9.6 Setting Standards of Achievement-</b> A medical school ensures that faculty members with appropriate knowledge and expertise set standards of achievement in each required learning experience in the medical education program.   |                   |                      |                           | A    | I  | R  | R                  | R                             | R                  | R       |                    |
| <b>9.7 Formative Assessment and Feedback-</b> A medical school ensures that each medical student is assessed and provided with formal formative feedback early enough during each required course or clerkship four or more weeks in length to allow sufficient time for remediation  |                   |                      |                           | A    | R  |  | I                  |                               | R                  | R       |                    |
| <b>9.8 Fair and Timely Summative Assessment-</b> A medical school has in place a system of fair and timely summative assessment of medical student achievement in each course and clerkship of the medical education program. Final grades are available within six weeks of the end of a course or clerkship.  |                   |                      |                           | A    | R  | R  | I                  |                               | R                  | R       |                    |
| <b>9.9 Single Standard for Promotion/Graduation and Appeal Process-</b> A medical school ensures that the medical education program has a single standard for the promotion and graduation of medical students across all locations and a fair and formal process for taking any action that may affect the status of a medical student, including timely notice of the impending action, disclosure of the evidence on which the action would be based, an opportunity for the medical student to respond, and an opportunity to appeal any adverse decision related to promotion, graduation, or dismissal. |                   |                      |                           | A    | R  | R  | I                  |                               | R                  | R       |                    |
| <b>Standard 10: Medical Student Selection, Assignment, and Progress-</b>  |                   |                      |                           |      |  |  |                    |                               |                    |         |                    |
| <b>10.1 Premedical Education/Required Coursework-</b> a medical school encourages potential applicants to the medical education program to acquire a broad undergraduate education that includes the study of the humanities, natural sciences, and social sciences, and confines its specific premedical course requirements to those deemed essential preparation for successful completion of its medical curriculum.  |                   |                      |                           |      |  |  | I                  |                               | A                  | R       |                    |
| <b>10.2 Final Authority of Admission Committee-</b> The final responsibility for accepting students to a medical school rests with a formally constituted admission committee. The authority and composition of the committee and the rules for its operation, including voting privileges and the definition of a quorum, are specified in bylaws or other medical school policies. Faculty members constitute the majority of voting members at all meetings. The selection of individual medical students for admission is not influenced by any political or financial factors.                           |                   |                      |                           |      |  |  | I                  |                               | A                  | R       |                    |
| <b>10.3 Policies Regarding Student Selection/Progress and Their Dissemination-</b> The faculty of a medical school establish criteria for student selection and develop and implement effective policies and procedures regarding, and make decisions about, medical student application, selection, admission, assessment, promotion, graduation, and any disciplinary action.   |                   |                      |                           |      |  |  | I                  |                               | A                  | R       |                    |
| <b>10.4 Characteristics of Accepted Applicants-</b> A medical school selects applicants for admission who possess the intelligence, integrity, and personal and emotional characteristics necessary for them to become competent physicians.  |                   |                      |                           | R    | R  | R  | I                  |                               | A                  | R       |                    |
| <b>10.5 Technical Standards-</b> A medical school develops and publishes technical standards for the admission, retention, and graduation of applicants or medical students with disabilities, in accordance with legal requirements.   |                   |                      |                           |      | R  | R  | I                  |                               | A                  | R       |                    |
| <b>10.6 Content of Informational Materials-</b> A medical school's catalog and other informational, advertising, and recruitment materials present a balanced and accurate representation of the mission and objectives of the medical education program, state the academic and other (e.g., immunization) requirements for the M.D. degree and all associated joint degree programs, provide the most   |                   |                      | R                         | A    | R  | R  | I                  |                               | R                  | R       |                    |





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| recent academic calendar for each curricular option, and describe all required courses and clerkships offered by the medical education program.  |  |  |  |  |  |     |  |   |   |  |  |
| 10.7 Transfer Student Qualifications- A medical school ensures that any student accepted for transfer or admission with advanced standing demonstrates academic achievements, completion of relevant prior coursework, and other relevant characteristics comparable to those of the medical students in the class that he or she would join.  |  |  |  |  |  | I   |  | A | R |  |  |
| 10.8 Transfer into the Final Year- A medical school accepts a transfer medical student into the final year of a medical education program only in rare and extraordinary personal or educational circumstances.  |  |  |  |  |  | I   |  | A | R |  |  |
| 10.9 Visiting Student Processing- A medical school verifies the credentials of each visiting medical student, maintains a complete roster of visiting medical students, approves each visiting medical student's assignments, provides a performance assessment for each visiting medical student, and establishes health-related protocols for such visiting medical students.  |  |  |  |  |  | I   |  | A | R |  |  |
| 10.10 Visiting Student Qualifications- A medical school ensures that any visiting medical student demonstrates qualifications comparable to those of the medical students he or she would join in those educational experiences and identifies the administrative office that fulfills this responsibility.  |  |  |  |  |  | I   |  | A | R |  |  |
| 10.11 Student Assignment- A medical school assumes ultimate responsibility for the selection and assignment of medical students to each location and/or parallel curriculum (i.e., track) and identifies the administrative office that fulfills this responsibility. A process exists whereby a medical student with an appropriate rationale can request an alternative assignment when circumstances allow for it.                                |  |  |  |  |  | I   |  | A | R |  |  |
| Standard 11: Medical Student Academic Support, Career Advising, and Educational Records  |  |  |  |  |  | I   |  | A | R |  |  |
| 11.1 Academic Advising- A medical school has an effective system of academic advising in place for medical students that integrates the efforts of faculty members, course and clerkship directors, and student affairs staff with its counseling and tutorial services and ensures that medical students can obtain academic counseling from individuals who have no role in making assessment or promotion decisions about them.                   |  |  |  |  |  | I   |  | A | R |  |  |
| 11.2 Career Advising- A medical school has an effective career advising system in place that integrates the efforts of faculty members, clerkship directors, and student affairs staff to assist medical students in choosing elective courses, evaluating career options, and applying to residency programs.   |  |  |  |  |  | I   |  | A | R |  |  |
| 11.3 Oversight of Extramural Electives- If a medical student at a medical school is permitted to take an elective under the auspices of another medical school, institution, or organization, a centralized system exists in the dean's office at the home school to review the proposed extramural elective prior to approval and to ensure the return of a performance assessment of the student and an evaluation of the elective by the student. |  |  |  |  |  | I   |  | A | R |  |  |
| 11.4 Provision of MSPE- A medical school provides a Medical Student Performance Evaluation required for the residency application of a medical student only on or after October 1 of the student's final year of the medical education program.  |  |  |  |  |  | I   |  | A | R |  |  |
| 11.5 Confidentiality of Student Educational Records- At a medical school, medical student educational records are confidential and available only to those members of the faculty and administration with a need to know, unless released by the student or as otherwise governed by laws concerning confidentiality.  |  |  |  |  |  | I,A |  |   |   |  |  |
| 11.6 Student Access to Educational Records- A medical school has policies and  |  |  |  |  |  | I,A |  |   |   |  |  |



**Compartmentalization of Decision Authority to Prevent Direct Conflict of Interest**

| Category of decision authority  | Board of Trustees | University President | University Vice President | Dean | Senior Associate Dean of Medical Education | Senior Associate Dean of Clinical Medicine | Other Deans/Chairs | Clinical Governance Committee | Faculty Committees | Faculty | Board of Directors |
|---|-------------------|----------------------|---------------------------|------|--|--|--------------------|-------------------------------|--------------------|---------|--------------------|
| <b>A = Approval</b> (integral position authority)   |                   |                      |                           |      |  |  |                    |                               |                    |         |                    |
| <b>AO = Approval on the Authority of Board of Trustees</b>  |                   |                      |                           |      |  |  |                    |                               |                    |         |                    |
| <b>I = In-charge</b> (execution, implementation, maintaining, monitoring, if more than one entities designated, then all designated entities have shared responsibility), and accountable to the Dean of College of Medicine.   |                   |                      |                           |      |  |  |                    |                               |                    |         |                    |
| <b>R = Recommendation</b> (proposing via committee action, advocacy, or supporting after review)  |                   |                      |                           |      |  |  |                    |                               |                    |         |                    |
| procedures in place that permit a medical student to review and to challenge his or her educational records, including the Medical Student Performance Evaluation, if he or she considers the information contained therein to be inaccurate, misleading, or inappropriate.   |                   |                      |                           |      |  |  |                    |                               |                    |         |                    |
| <b>Standard 12: Medical Student Health Services, Personal Counseling, and Financial</b>   |                   |                      |                           |      |  |  |                    |                               |                    |         |                    |
| <b>12.1 Financial Aid/Debt Management Counseling/ Student Educational Debt-</b> A medical school provides its medical students with effective financial aid and debt management counseling and has mechanisms in place to minimize the impact of direct educational expenses (i.e., tuition, fees, books, supplies) on medical student indebtedness.  |                   |                      |                           | A    |  |  | I                  |                               | R                  | R       |                    |
| <b>12.2 Tuition Refund Policy-</b> A medical school has clear, reasonable, and fair policies for the refund of a medical student's tuition, fees, and other allowable payments  |                   |                      |                           | A    |  |  | I                  |                               | R                  | R       |                    |
| <b>12.3 Personal Counseling/Well-Being Programs-</b> A medical school has in place an effective system of personal counseling for its medical students that includes programs to promote their well-being and to facilitate their adjustment to the physical and emotional demands of medical education.  |                   |                      |                           | A    |  |  | I                  |                               | R                  | R       |                    |
| <b>12.4 Student Access to Health Care Services-</b> A medical school provides its medical students with timely access to needed diagnostic, preventive, and therapeutic health services at sites in reasonable proximity to the locations of their required educational experiences and has policies and procedures in place that permit students to be excused from these experiences to seek needed care.   |                   |                      |                           | A    |  |  | I                  |                               | R                  | R       |                    |
| <b>12.5 Non-Involvement of Providers of Student Health Services in Student Assessment/ Location of Student Health Records-</b> The health professionals who provide health services, including psychiatric/psychological counseling, to a medical student have no involvement in the academic assessment or promotion of the medical student receiving those services. A medical school ensures that medical student health records are maintained in accordance with legal requirements for security, privacy, confidentiality, and accessibility. |                   |                      |                           |      |  |  | I                  |                               |                    |         |                    |
| <b>12.6 Student Access to Health and Disability Insurance-</b> A medical school ensures that health insurance is available to each medical student and his or her dependents and that each medical student has access to disability insurance.  |                   |                      | I                         | A    |  |  | R                  |                               |                    |         |                    |
| <b>12.7 Immunization Guidelines-</b> A medical school follows accepted guidelines in determining immunization requirements for its medical students.  |                   |                      |                           | A    |  |  | I,R                |                               |                    |         |                    |
| <b>12.8 Student Exposure Policies/Procedures-</b> A medical school has policies in place that effectively address medical student exposure to infectious and environmental hazards  |                   |                      |                           | A    |  |  | I,R                |                               |                    |         |                    |