

Conflict of Interest Situations with Possible Management Plans

Consulting Relationship

Faculty and staff have the right to acquire and retain outside interests or relationships of a professional, personal, or economic nature that do not conflict with University interests or the individual employee's commitment to the University. The success of relationships between industry and academia are critically dependent upon maintaining openness, scientific integrity and independence. Prior to entering into a consulting or other outside work situation, faculty and staff must consider the following:

- Faculty are allowed up to 1 day a week or up to 20% effort per faculty handbook policy.
- Each faculty/staff member is expected to know his/her **school/college/unit and faculty handbook policy** on outside professional activities and to report outside activities in compliance with that policy.
- Faculty and staff members with a 50% or more appointment owe their primary loyalty to the University.
- A University employee may not use his/her University position for his/her personal financial benefit or for the benefit of family members to the detriment of the University. This implies that a faculty/staff member must not allow outside activities and interests to compromise the educational program to the student's detriment.
- A University employee may not use University facilities or resources on behalf of an outside interest without an explicit agreement with the University, including provisions to repay the cost of those resources.
- Each faculty/staff member must consider the appropriateness of UNM student/trainees participation in the consulting or other outside work situation.

Example 1:

Company A wishes to sponsor research into the University under the direction of Professor Z. The focus of the research is to perform basic research methodologies to develop improved methods for strengthening and improving the durability of concrete used in highways. Company A and Professor Z have an ongoing consulting relationship (for less than \$10,000) clearly unrelated to the focus of the UNM side of the company sponsored research project. No UNM students or trainees are assigned or supported by this sponsored research project.

This situation presents *minimal risks* and falls into what the COI committees refer to as Category I, requiring disclosure to the appropriate conflict of interest review committee.

Example 1a: Consulting with student element

The UNM side of the company sponsored project (described above) will provide support for one graduate student under the direct supervision of Professor Z. This is a situation that requires review and a management plan.

Management solutions may include the following:

- Appointing another faculty member (with no connection to the company) to serve as thesis advisor of the student, if the focus of the thesis is based on this research.
- Serving as co-thesis advisor with another faculty member (with no connection to the company), if the focus of the thesis is based on this research.

Example 1b: Consulting with significant risk

The UNM side of the company sponsored research project (described above) is directly related to the work conducted by Professor Z as a consultant to the company.

This situation presents *significant risks*. The example solutions provided below are intended to be a guide for demonstrating how particular conflict situations may be managed [note: the details of some situations may make COI management unworkable and the project will not commence]. The examples are not intended to be all-inclusive as each individual situation may require a greater or lesser degree of management based upon the elements of risk presented.

- A. Appoint a different faculty member, who has no connection to the company, as PI. The new PI oversees all aspects of the sponsored project to the University. This minimizes the conflict of interest for Professor Z, who may decide to be involved in the project as a representative of the company.
- or
- B. Appoint a different faculty member, who has no connection to the company, as PI and allow the original faculty member (Professor Z) to serve as co-investigator. The new PI oversees all aspects of the sponsored project (see notes below).
- or
- C. If the technical work requires that Professor Z remain as PI, another individual with no connection to the company is appointed to oversee the performance of the sponsored project (although this individual may not participate in the research activity).
- D. The consultant relationship between Professor Z and the company can be severed and the research commence.

Notes:

For examples B & C the following additional management conditions may apply:

Professor Z will need to provide a written statement that clearly describes and distinguishes between his/her obligations as a key investigator on the sponsored project and his/her obligations to the company as a consultant. Professor Z does not participate in any decision-making as a representative of the company

sponsor and would disclose his/her company connection to lab staff, students, oversight committees (IRB, IACUC, COI), Purchasing, as well as in any publications about the research. Annual evaluations of staff or key personnel involved in the project would not be the sole responsibility of Professor Z; additional oversight would be provided by a higher-level academic administrator. If human subjects are involved in the research, the new PI or another individual with no connection to the company would oversee all aspects of human subject participation

Sponsored Research Projects/Subcontract Agreements

The Statement of Work and/or contractual agreement in a research/subcontract agreement is critical since it determines:

- Intellectual property rights that will be offered to the sponsor
- Publications that may be reviewed by the sponsor
- Overlap with other research
- Need to use existing intellectual property
- Need to access sponsor confidential information
- Cost of and use of various personnel
- Compliance conditions

Example 1: Subcontract with minimal risk

Professor Y holds equity in a local for-profit company. The company applied for and received an award from NIH/NSF/DOD/NASA, etc., and wishes to subcontract a portion of the work into the University under the direction of Professor C. Professor C has no financial interest in the company and is not a consultant nor a member of the company's Board of Director's or Scientific Advisory Board, etc. Professor Y will not be involved on the UNM side of the company-sponsored research project in his/her capacity as a University employee and has no oversight authority over Professor C. Likewise, Professor C has no oversight authority over Professor Y.

This situation presents *minimal risks* and falls into what the COI committees refer to as Category I, requiring disclosure as sufficient management.

Example 1a: Subcontract with student element

A UNM graduate student will participate in the company-sponsored research project described above under the direction and supervision of Professor Y. This is a situation that needs review and a management plan.

Management solutions may include the following:

- Appointing another faculty member (with no connection to the company) to serve as thesis advisor of the student, if the focus of the thesis is based on this research.
- Serving as co-thesis advisor with another faculty member (with no connection to the company), if the focus of the thesis is based on this research.

Example 1b: Subcontract with a conflicted Key Investigator

The UNM side of the company-sponsored research project (described above) will be under the direction of Professor Y.

This situation presents *significant risks*. The example solutions provided below are intended to be a guide for demonstrating how particular conflict situations may be managed [note: the details of some situations may make conflict of interest (COI)

management unworkable and the project will not commence]. **The examples are not intended to be all-inclusive as each individual situation may require a greater or lesser degree of management based upon the elements of risk presented.**

A. Appoint a different faculty member, who has no connection to the company, as PI. The new PI oversees all aspects of the subcontract to the University. This minimizes the conflict of interest for Professor Y (as in Example 1 above), who may decide to be involved in the project as a representative of the company.

or

B. Appoint a different faculty member, who has no connection to the company, as PI and allow the original faculty member (Professor Y) to serve as co-investigator. The new PI oversees all aspects of the subcontract. This becomes a managed conflict of interest for Professor Y (see notes below).

or

C. If the technical work requires that Professor Y remain as PI, another individual with no connection to the company is appointed to oversee the performance of the subcontract including research reporting and financial oversight (although this individual may not participate in the research activity) (see notes below).

D. The consultant relationship between Professor Z and the company can be severed and the research commence.

Notes:

1. For examples B & C the following additional management conditions may apply:

Professor Y does not participate in any decision-making as a representative of the company sponsor and would disclose his/her company connection to lab staff, students, oversight committees (IRB, IACUC, COI), Purchasing, as well as in any publications about the research. Annual evaluations of staff or key personnel involved in the project would not be the sole responsibility of Professor Y; additional oversight would be provided by a higher-level academic administrator. If human subjects are involved in the research, the new PI or another individual with no connection to the company would oversee all aspects of human subject participation.

SBIR and STTR Programs in Federal Research Agencies

The Small Business Innovation Research (SBIR) program funds early-stage research and development at small technology companies. Note that to participate in the SBIR program:

- during Phase I, a minimum of two-thirds (or 67%) of the effort must be performed by the proposing firm; a minimum of one-half (or 50%) of the effort in Phase II
- the Principal Investigator must spend more than one-half (or 50%) of their time employed by the proposing firm

The Small Business Technology Transfer (STTR) program is similar in structure to the SBIR but funds *cooperative* research and development projects involving a small business and a research institution. Note that to participate in the STTR program:

- the small business must perform a minimum of 40% of the work and the research institution a minimum of 30% of the work in both Phase I and Phase II
- the small business must manage and control the STTR funding agreement (i.e., serve as the prime contractor with the Government)

Example 1:

Company X applies for and receives an SBIR/STTR award. Professor K is part-owner and President of Company X. Professor K will NOT be involved as the PI or a Key Investigator in the research being conducted at the UNM and has no reporting or oversight relationship with any of the key personnel or students/trainees assigned to the UNM side of the company sponsored research project.

This situation presents *minimal risks* and falls into what the conflict of interest committees refer to Category I, requiring disclosure as sufficient management.

Example 1a: Subcontract with student element

A UNM graduate student will participate in the company-sponsored research project described above under the direction and supervision of Professor K. This is a situation that needs review and a management plan.

Management solutions may include the following:

- Appointing another faculty member (with no connection to the company) to serve as thesis advisor of the student, if the focus of the thesis is based on this research.
- Serving as co-thesis advisor with another faculty member (with no connection to the company), if the focus of the thesis is based on this research.

Example 1b: Subcontract with a conflicted Key Investigator

The UNM side of the company sponsored project (described above) will be under the direction of Professor K.

This situation presents *significant risks*. The example solutions provided below are intended to be a guide for demonstrating how particular conflict situations may be managed [note: the details of some situations may make conflict of interest (COI) management unworkable and the project will not commence]. The examples are not intended to be all-inclusive as each individual situation may require a greater or lesser degree of management based upon the elements of risk presented.

A. Appoint a different faculty member, who has no connection to the company, as PI. The new PI oversees all aspects of the subcontract to the University. This minimizes the conflict of interest for Professor K (as in Example 1 above), who may decide to be involved in the project as a representative of the company.

or

B. Appoint a different faculty member, who has no connection to the company, as PI and allow the original faculty member (Professor K) to serve as co-investigator. The new PI oversees all aspects of the subcontract including research reporting and financial oversight. This becomes a managed conflict of interest for Professor K (see notes below).

or

C. If the technical work requires that Professor K remain as PI, another individual with no connection to the company is appointed to oversee the performance of the subcontract (although this individual may not participate in the research activity) (see notes below).

Notes:

1. For examples B & C the following additional management conditions may apply:

Professor K does not participate in any decision-making as a representative of the company sponsor and would disclose his/her company connection to lab staff, students, oversight committees (IRB, IACUC, COI), Purchasing, as well as in any publications about the research. Annual evaluations of staff or key personnel involved in the project would not be the sole responsibility of Professor K; additional oversight would be provided by a higher-level academic administrator. If human subjects are involved in the research, the new PI or another individual with no connection to the company would oversee all aspects of human subject participation.

Students/Trainees

The mission of the University of New Mexico is to create, communicate, preserve, and apply knowledge in the public interest. Education and mentoring of students is central to fulfillment of the University's mission and, in fact is one of the most important responsibilities assumed by faculty members. More recently, University support for transfer of knowledge to the commercial sector in the public interest has led to increasingly complex roles for faculty members and students in relationships to industry-sponsored research, technology transfer and entrepreneurship. A student's/trainees' participation in a project supported by or requiring collaboration with a faculty-owned company should be under the supervision of a faculty member with no financial interests in such company. Faculty and staff cannot enter into agreements related to their University responsibilities that limit publication, dissemination, or access to information unless approved by the University.

Example 1:

Professor K holds equity in a local company. The company wishes to participate as one of many sponsors of a project aimed at supporting the Ph.D. thesis of a graduate student. Professor K will not be involved in the UNM side of the company sponsored research project in his/her capacity as a University employee and is not a member of the graduate student's thesis committee.

This situation presents minimal risks and falls into what the conflict of interest committees refer to as a Category I, requiring disclosure as sufficient management.

Example 1a: Student situation with significant risk

In Example 1 above, Professor K is sole chair of the graduate student's thesis committee. This presents an unacceptable conflict.

Management solutions may include the following:

- Appointing another faculty member (with no connection to the company) to serve as thesis advisor of the student, if the focus of the thesis is based on this research.
- Serving as co-thesis advisor with another faculty member (with no connection to the company), if the focus of the thesis is based on this research.

Memberships on Board of Directors and/or Scientific Advisory Boards

Example 1: Sponsored Research with minimal risk

UNM has applied for and received an award from NIH which will include a subcontract to a local company for a portion of the work. UNM's NIH sponsored project will be under the direction of Professor Q. Professor Q has no financial interest in the company receiving the subcontract, is not a consultant, Board of Director or Scientific Advisory Board member. However, Professor G serves as a Board of Director for the company receiving the subcontract from the UNM. Professor G will not be involved in UNM's NIH sponsored project in his/her capacity as a University employee and has no oversight authority over Professor Q. Likewise, Professor Q has no oversight authority over Professor G.

This situation presents *minimal risks* and falls into what the COI committees refer to as a Category I, requiring disclosure as sufficient management.

Example 1a: Sponsored Project with student element

UNM's NIH sponsored project (described above) will also provide support for a graduate student under the direction and supervision of Professor G. This is a situation that needs review and a management plan.

Management solutions may include the following:

- Appointing another faculty member (with no connection to the company) to serve as thesis advisor of the student, if the focus of the thesis is based on this research.
- Serving as co-thesis advisor with another faculty member (with no connection to the company), if the focus of the thesis is based on this research.

Example 1b: Sponsored Project with a conflicted Key Investigator

The UNM's NIH sponsored project (described above) will be under the direction of Professor G.

This situation presents *significant risks*. The example solutions provided below are intended to be a guide for demonstrating how particular conflict situations may be managed [note: the details of some situations may make COI management unworkable and the project will not commence]. The examples are not intended to be all-inclusive as each individual situation may require a greater or lesser degree of management based upon the elements of risk presented.

- A. Appoint a different faculty member, who has no connection to the company, as PI. The new PI oversees all aspects of the sponsored project to the University. This minimizes the conflict of interest for Professor G (as in Example 1 above), who may decide to be involved in the project as a representative of the company.

or

- B. Appoint a different faculty member, who has no connection to the company, as PI and allow the original faculty member (Professor G) to serve as co-investigator. The new PI oversees all aspects of the sponsored project. This becomes a managed conflict of interest for Professor G (see notes below).

or

- C. Although the least desirable, if the technical work requires that Professor G remain as PI, another individual with no connection to the company is appointed to oversee the performance of the sponsored project (although this individual may not participate in the research activity) (see notes below).

or

- D. The consultant relationship between Professor G and the company can be severed and the research commence.

Notes:

For examples B & C the following additional management conditions may apply:

Professor G does not participate in any decision-making as a representative of the company sponsor and would disclose his/her company connection to NIH, lab staff, students, oversight committees (IRB, IACUC, COI), Purchasing, as well as in any publications about the research. Annual evaluations of staff or key personnel involved in the project would not be the sole responsibility of Professor G; additional oversight would be provided by a higher-level academic administrator. If human subjects are involved in the research, the new PI or another individual with no connection to the company would oversee all aspects of human subject participation.

Royalties

As a public institution, the University of New Mexico is committed to teaching, research, and service. A key component of the University's mission is the application of knowledge to programs of general public interest. Technology transfer, as a beneficial outcome of teaching and research, is an application of knowledge that responds to many societal needs. By recognizing and supporting activities related to technology transfer and intellectual property development, the University acknowledges that these activities are an integral component of its mission. Faculty members, through their ongoing research activities, play a key role in supporting this component of the University's mission.

Example 1: Royalty interest with minimal risk

Professor R is the owner of a local company that wants to license University-owned technology invented by Professor D. Through the University's revenue distribution plan, Professor D will receive royalties on the technology licensed to the company. No use of University services or facilities, nor any assignments of University employees, is obligated or contemplated in the agreement and Professor D has no financial or management interest in the company.

This situation presents *minimal risk* and falls into what the COI committees refer to as a Category I.

Example 2: Royalty interest with student element

In the proposed license agreement (described in example 1 above), Professor R and a graduate student are co-inventors of the technology to be licensed to Professor R's company. Professor R is the graduate student's academic advisor. This is a situation that needs review and a management plan.

Management solutions may include the following:

- A student may not be simultaneously employed by an outside entity in which their faculty advisor has a significant financial interest in.
- Appointing another faculty member (with no connection to the company) to serve as thesis advisor of the student, if the focus of the thesis is based on this research.

This situation presents *significant risks*. The example solutions provided below are intended to be a guide for demonstrating how particular conflict situations may be managed [note: the details of some situations may make COI management unworkable and the project will not commence]. The examples are not intended to be all-inclusive as each individual situation may require a greater or lesser degree of management based upon the elements of risk presented.

- A. Appoint a different faculty member, who has no connection to UNM, as PI of the project at the University of ABCZ. The new PI oversees all aspects of the subcontract to the University. This minimizes the conflict of interest for Professor Z.

or

- B. Appoint a different faculty member, who has no connection to the University of ABCZ, as PT of the UM project and allow the original faculty member (Professor Z) to serve as co-investigator. The new PT oversees all aspects of the subcontract. This becomes a managed conflict of interest for Professor Z (see notes below).

or

- C. Although the least desirable, if the technical work requires that Professor Z remain as PT at both the UM and the University of ABCZ, another individual with no connection to the University of ABCZ is appointed to oversee the performance of the subcontract (although this individual may not participate in the research activity) (see notes below).
- D. The consultant relationship between Professor G and the company can be severed and the research commence.

Notes:

For examples B & C the following additional management conditions may apply:

Professor Z would disclose his/her University of ABCZ connection to lab staff, students, oversight committees (IRB, IACUC, COI), as well as in any publications about the research. Annual evaluations of staff or key personnel involved in the project would not be the sole responsibility of Professor Z; additional oversight would be provided by a higher-level academic administrator. If human subjects are involved in the research, the new PT or another individual with no connection to the University of ABCZ would oversee all aspects of human subject participation.

President Chief Executive Officer Secretary Chief Scientific Officer Chief Financial Officer

Example 1: Sponsored Project with minimal risk

Professor C is the President and Chief Scientific Officer of a local for-profit company. The company wishes to sponsor research into the University under the direction of Professor A in the Department of Chemistry. Professor A has no financial interest in the company, is not a consultant nor a member of the company's Board of Director's or Scientific Advisory Board, etc. Professor C will not be involved in the UNM side of the company sponsored research project in his/her capacity as a University employee and has no oversight authority over Professor A.

This situation presents *minimal risks* and falls into what the COI committees refer to as "Administrative Shunt" category requiring disclosure as sufficient management.

Example 1a: Sponsored Project with student element

The UNM side of the company sponsored project (described above) will also provide support for a GSRA under the direction and supervision of Professor C. This presents an unacceptable conflict (see Operating Principle #4).

Management solutions may include the following:

- Appointing another faculty member (with no connection to the company) to serve as thesis advisor of the student, if the focus of the thesis is based on this research.
- Serving as co-thesis advisor with another faculty member (with no connection to the company), if the focus of the thesis is based on this research.

Example 1b: Sponsored Project with a conflicted Key Investigator

The UNM side of the company sponsored research project (described above) will be under the direction of Professor C (see Operating Principle #5).

This situation presents *significant risks*. The example solutions provided below are intended to be a guide for demonstrating how particular conflict situations may be managed [note: the details of some situations may make COI management unworkable and the project will not commence]. The examples are not intended to be all-inclusive as each individual situation may require a greater or lesser degree of management based upon the elements of risk presented.

- A. Appoint a different faculty member, who has no connection to the company, as PI. The new PI oversees all aspects of the sponsored project to the University. This minimizes the conflict of interest for Professor C (as in Example 1 above), who may decide to be involved in the project as a representative of the company.

or

- B. Appoint a different faculty member, who has no connection to the company, as PI and allow the original faculty member (Professor C) to serve as co-investigator. The new PI oversees all aspects of the sponsored project. This becomes a managed conflict of interest for Professor C (see notes below).

or

- C. Although the least desirable, if the technical work requires that Professor C remain as PI, another individual with no connection to the company is appointed to oversee the performance of the sponsored project (although this individual may not participate in the research activity) (see notes below).

Notes:

For examples B & C the following additional management conditions may apply:

Professor C does not participate in any decision-making as a representative of the company sponsor and would disclose his/her company connection to lab staff, students, oversight committees (IRB, UCUCA), Purchasing, as well as in any publications about the research. Annual evaluations of staff or key personnel involved in the project would not be the sole responsibility of Professor C; additional oversight would be provided by a higher-level academic administrator. If human subjects are involved in the research, the new PI or another individual with no connection to the company would oversee all aspects of human subject participation.