**SAMPLE – recognize that not every COI is the same. COI’s include activities in which you may receive financial interest or advantage for yourself, your immediate family, your close associates, or a business over which you or your family has a direct or indirect financial interest. Some COI’s may involve a faculty start-up company, a family members’ ownership interest in a sponsor or a company that provides goods or services, inclusion of your spouse/partner on a funded project, etc. So please take time to carefully review and modify this SAMPLE as necessary, deleting unnecessary sections via a red-line version, to propose a plan to manage your COI that will fit your particular circumstances!**

**CONFLICT OF INTEREST (COI) MANAGEMENT PLAN**

**Investigator’s Name**:

**Department/Center Affiliation:**

**Entity with which the Investigator Desires to Establish a Relationship**:

**Reason for Management Plan** (check all that apply)**:**

\_\_\_\_\_ Financial interest in an entity that engages in activities that overlap with the Investigator’s university responsibilities

\_\_\_\_\_ Management role in an entity that engages in activities that overlap with the Investigator’s university responsibilities

\_\_\_\_\_ Consulting activities for an entity that sponsors the Investigator’s university scholarly activities

\_\_\_\_\_ Consulting activities for an entity with a financial interest in the outcome of the Investigator’s scholarly activities

\_\_\_\_\_ Other – including activities that include participation of a family member (including a spouse/partner) in a proposal or funded activity (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Effective Period of this Management Plan** (one year):

**Background** -**The Entity and the relationship of the employee to the Entity**

**Company Name**:

**Month/Year of incorporation**:

**Company Location**:

**Founders**:

**Investigator’s Role**:

**Other Company Officers**:

**About the Company**:

**1.** **Protection of NDSU Personnel under the Investigator’s Supervision**

Because university personnel (“Personnel”) under the supervision of the Investigator have the potential to be impacted by the Investigator’s involvement with the Entity, steps must be taken to protect them. “Personnel” includes students, postdocs, technicians, visiting scientists, other support staff, etc., engaged in research or other activities under the Investigator’s supervision in his/her university role.

*Notification Requirements*

1. The Investigator is responsible for ensuring that all Personnel engaged in research or other activities under the Investigator’s supervision are notified of the relationship with the Entity, the existence of this COI Management Plan (hereinafter “Plan”), and the names of *<insert “the COI Oversight Manager”* or *“ the members of the COI Management Committee”*>, as provided below, for the Personnel to notify with any concerns.
2. The Investigator’s notification to the Personnel shall occur within 30 days of the acceptance of this Plan and shall occur immediately upon the addition of new Personnel under the Investigator’s supervision. **The Investigator shall provide written notification to his/her** <insert “***COI Oversight Manager”*** or **“*COI Management Committee Members”***> **of compliance with this notification requirement.**
3. In addition, the Investigator shall provide all NDSU graduate students working in the Entity (that is, employed by the Entity) or for the Entity (that is, on a funded or unfunded project for the Entity) and their **major professors** a complete copy of Section 1 of this Plan, no less than 30 days from the acceptance of this Plan or the appointment of the student to a position in or for the Entity.
4. Personnel under the Investigator’s supervision should notify the <insert “*COI Oversight Manager*” or “*Chair or members of the COI Management Committee*”> if they feel their involvement with the Entity (or their lack of involvement) in any way adversely affects their academic progress or employment status.

*Protections*

1. The Investigator’s relationship with the Entity may not place restrictions on the scholarly and research activity of the Personnel, including the ability to receive, analyze, or interpret data and to publish on the research and scholarly activity.
2. The Entity cannot prevent or inhibit a student researcher from meeting the applicable degree requirements.
3. The Investigator may not serve as the major or co-major professor for a graduate student who works in the Entity (are paid by) or for the Entity (such as on a grant to NDSU from the Entity). The Investigator may serve on their Program of Study committee. **The person serving as major professor must agree to take full responsibility for the progress of the graduate student in their degree program and protection of the student from any adverse effects of the Investigator’s involvement with the Entity.**
4. Because of their generally greater level of independence and experience, the Investigator may supervise technicians, visiting scientists and postdoctoral associates in his/her university lab who also work in or for the Entity.

*Involvement of Personnel in the Entity*

1. The Personnel may not participate in any activity of or receive any compensation from the Entity, including research sponsored by the Entity, without approval from the <insert “*COI Oversight Manager*” or “*COI Management Committee*”>.
2. The Investigator must direct any Personnel with a significant financial interest or management role in the Entity to make an annual disclosure of outside activities in accordance with the NDSU COI Policy, if they have not already done so. The disclosure shall be reviewed by the <insert “*COI Oversight Manager*” or “*COI Management Committee*”>, as well as any additional reviewers that may be required for a COI Oversight Manager or COI Management Committee for the Personnel. The review may result in a COI Management Plan for the Personnel.

*Special Rights and Responsibilities of Graduate Students and Major Professors*

1. Graduate students who work in or for the Entity are especially vulnerable because of the potential for the interests of the Entity to conflict with the student’s educational interests. Students in this situation and their major professors must take special precautions to assure the student’s relationship to the Entity does not harm the students’ academic progress or chances for a successful career.
2. It is the right of every student working in or for the Entity to have as a major professor someone in no way affiliated with the Entity who has the authority, interest, and time to assure that the student’s educational interests are protected.
3. It is the student’s responsibility to meet with their major professor to discuss their progress and concerns; the student should document when the meetings occur in case questions arise. The students are also strongly encouraged to bring any unresolved concerns arising from their relationship to the Entity forward to the Investigator’s <insert “*COI Oversight Manager*” or “*COI Management Committee*”>.
4. It is the responsibility of major professors of students who work in or for the Entity to arrange meetings with the students to assess the progress of the students and discuss any concerns, especially those arising from their relationship to the Entity. The major professor should document when the meetings occur. The major professors are also encouraged to bring forward to the Investigator’s <insert “*COI Oversight Manager*” or “*COI Management Committee*”> any questions or unresolved concerns.
5. The Investigator will notify in writing the <insert “*COI Oversight Manager*” or “*COI Management Committee*”> immediately upon completion of this requirement. The notification will include the names of the students and their major professors.

**2. Protection of** **Research Subjects and Compliance**

All projects involving human subjects require special protections for the subjects of the study and must be approved by the Institutional Review Board (IRB). IRB approval must be obtained before any project involving human subjects is undertaken. For projects involving conflicts of interest or the potential for perception of conflicts of interest, the IRB has the authority to establish restrictions in addition to those described in this document. This may include, but is not limited to, disclosure of the conflict in informed consent documents.

Similarly, all research involving animals and/or biohazards must be approved by the Institutional Animal Care and Use Committee (IACUC) and the Institutional Biosafety Committee (IBC), respectively, prior to initiating the research. Both the IACUC and IBC have the authority to establish restrictions in addition to those specified in this document.

**3.** **Sponsored Projects Directly or Indirectly Involving the Entity**

An appropriate COI Management Plan must be in place before NDSU will accept any support for a project in which a potential financial or management conflict has been identified. This includes projects in which funds or in-kind support is exchanged between NDSU and the Entity (direct involvement), as well as projects which, depending on the outcome, could be perceived as benefiting the Entity (indirect involvement). An example of the latter is an NIH grant to test pharmaceuticals given to an investigator receiving significant consulting fees from a pharmaceutical manufacturer.

At a minimum, the restrictions identified below will apply to all COI Management Plans, but the <insert “*COI Oversight Manager*” or “*COI Management Committee*”> may impose additional restrictions. The minimum restrictions are:

1. All of the university's activity with the Entity must be conducted under formal university agreements, such as sponsored research agreements.
2. The Investigator, and NDSU personnel reporting to the Investigator, normally may not serve as a PI or Co-PI of an NDSU project if the Investigator or any member of his/her immediate family consults for, has a significant financial interest in or a management role in the Entity, such as on the Entity's board of directors;
3. If the Investigator (or his/her family member) currently has a consulting relationship with, management role in or significant financial interest in the Entity and it is not feasible to transfer the PI or Co-PI role to another person without a conflict, a plan shall be developed by the <insert “*COI Oversight Manager*” or “*COI Management Committee*”> to manage the conflict. Possible plans include:
	* 1. The Investigator’s or family member’s transition out of the consulting relationship, management role or financial relationship with the Entity as soon as possible; or,
		2. The establishment of a Fiscal and/or Scientific Oversight Committee to monitor the conduct of the project.
4. The Investigator may participate on the Entity's scientific advisory board (if any), as long as that participation does not create other concerns, such as confusion in the ownership of intellectual property. The Investigator will recuse him/herself from funding decisions by the scientific advisory board which involve his/her university activities.
5. All intellectual property developed as part of the described project, which may be owned by the university or by the Entity, will be disclosed to both parties to assure ownership matters are addressed appropriately.
6. The Investigator will recuse him/herself from university activities and/or sponsored projects that could reasonably be seen as being in competition with the activities or projects of the Entity.
	* 1. If the activities of the Entity could be seen as being in competition with the Investigator’s university activities, and if such activities are a required part of the Investigator’s position responsibilities, the Investigator may need to either resign his/her university position or end his/her affiliation with the Entity.
		2. If the goals and objectives of sponsored funding received by the Investigator overlap with the projects of the Entity, all responsibility for the sponsored projects shall be transferred to independent parties not involved in the Entity and not reporting to the Investigator. Such transfers will require the approval of the sponsor. If the sponsor does not approve the transfer of responsibilities, the Investigator may need to either return the funding or end his/her affiliation with the Entity.

**4. Intellectual** **Property**

In accordance with NDSU policy, all intellectual property generated using university funds, including contracts, grants and gifts, belong to the University, except as specified otherwise in the terms and conditions of the funding agreement.

The Investigator shall disclose intellectual property generated using university funds to the Technology Transfer Office (TTO). The disclosures must be in a timely manner to permit patent protection, if such protection is deemed appropriate by TTO.

The Investigator will refrain from using his/her university research results in his/her Entity activities until there has been a review of any intellectual property resulting from the research by the NDSU TTO and a license obtained, or, if no intellectual property exists, then after the results have been disclosed publicly.

**5.** **Personal Commitments**

Investigator must discuss and receive permission from his/her department chair for plans to use regular University working hours to work for the Entity. The department chair may grant permission if he/she determines that:

1. the amount of University time used is consistent with University policy (total consulting from all sources may not exceed one day per month)
2. the Investigator will be able to meet all his/her University work commitments
3. the activity will advance the skills and abilities of the Investigator, with resultant benefit to the department, college or university, and
4. the activity is not otherwise detrimental to the department, college or university.

University holidays, vacations, nights and weekends (unless the latter are your normal working hours) may be used for Entity activities.

Investigators supporting themselves on sponsored grants or contracts during the summer or other times are reminded that they may not use time paid for by a grant or contract for activities other than those specified in the grant or contract. This includes, but is not limited to, other research projects, teaching, administration, consulting, vacation, Entity activities, etc.

**6.** **Publications and Presentations**

Although publications may be briefly delayed (maximum of 120 days) for the purpose of pre-publication review and intellectual property protection, the relationship with the Entity may not restrict publications or presentations.

The Investigator and researchers must disclose their relationship with the Entity in publications and presentations in their university role wherever the content of the publication or presentation could be perceived to benefit the Entity. This includes publications or presentations describing research, product comparisons, or recommendations relevant to the activities of the Entity or the Entity’s competitors.

**7. University Resources (****Facilities, Services and Personnel)**

The Entity shall not direct the use of university resources. Examples include: university-owned equipment in the Investigator's laboratory and graduate students and other personnel paid on grants from the Entity to the University.

The Entity shall not use university addresses, email addresses, phones, web sites, stationary, trademarks, faxes or other university property or services on behalf of the Entity or in any way that would imply university endorsement of the Entity or its products or services.

The Investigator shall take special care to not use university computers for Entity activities or to store Entity data on university computers or university data on Entity computers. The failure to keep Entity and university computer use separate can result in disputes over data ownership.

Use of university facilities or services by the Entity must be in compliance with all relevant university policies pertaining to use by external parties. Arrangements for use of university facilities or services must be made through the department chair and the Vice President for Business and Finance and in most circumstances will require a written agreement. This includes use of computers, laboratory equipment and supplies that reside in the Investigator’s university laboratory. Investigator should also establish a separate email address and phone number to use for Entity business. Incidental use of university phones and internet access is acceptable.

**8. <**insert “***COI Oversight Manager***” or “***COI Management Committee***”> **Review Procedures**

The <insert “*COI Oversight Manager*” or “*COI Management Committee*”> will establish a case file for each COI Management Plan and will monitor compliance with the Plan. To that end, the Investigator must meet at least once per year (an Annual Meeting) with the <insert “*COI Oversight Manager*” or “*COI Management Committee*”> to review information related to the Investigator's relationship with the Entity, its influence on the Investigator's university activities, and compliance with the terms of the COI Management Plan. Prior to the Annual Meeting, the Investigator will submit a written annual report to the <insert “*COI Oversight Manager*” or “*COI Management Committee*”> addressing these issues.

Fiscal and Scientific Oversight Committees, if required by this Plan, shall meet quarterly to assure the proper conduct of the research.

<insert “*Name of COI Oversight Manager*” or “*Members of the COI Management Committee*”, and identify below. Examples of members for a COI Management Committee could include: an Associate Dean for Research, Department Head/Chair, other faculty with relevant technical expertise, representatives from central administrative units, personnel from outside of NDSU, etc.>

**9.** **Changes in Status**

The Investigator will notify the <insert “*COI Oversight Manager*” or “*COI Management Committee*”> of any and all changes in his/her relationship with the Entity (e.g., the name of the Entity changes or the Investigator becomes a Board Member).

**10.** **Other**

Please use this section to address other concerns or unusual circumstances that need oversight.

**Approved by the** <insert “***COI Oversight Manager***” or “***Chair of the COI Management Committee***”>

Printed Name: Date

Title:

**Agreed to by Investigator:**

By signing this COI Management Plan, I understand that failure to disclose relevant information and/or failure to abide by the terms of the plan could constitute academic misconduct.

Name: Date: