Simplified Strategies for Success: Developing Effective Conflict of Interest Management Plans

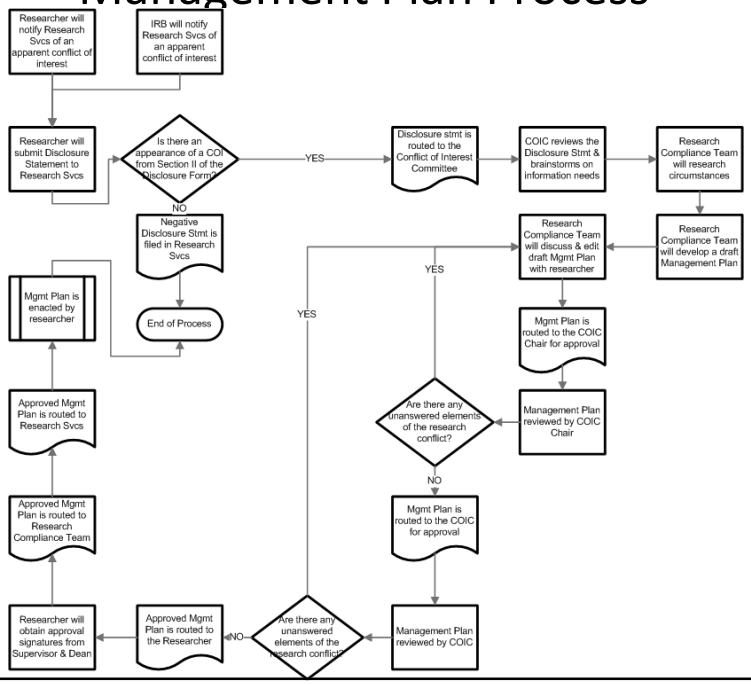
Kerry Borawski
Kathleen B. Merlo
Saint Louis University

Sponsors the Billiken's Research Work

Compensates the Billiken for Unrelated Consulting Work

Management Plan, Cafeteria Style

Management Plan Process



Conflict of Interest Talking Points

Management Plan Structure

- Section 1 – Employee Information
- Section 2 – Sponsor Information
- Section 3 – Management Plan
- Section 4 – Management Plan Participants
- Section 5 – Approval Signatures
- Addendum – Study Specific Details

SAINT LOUIS UNIVERSITY

SAINT LOUIS UNIVERSITY

CONFLICT OF INTEREST IN RESEARCH MANAGEMENT PLAN

SECTION 1 - EMPLOYEE INFORMATION:

Investigator Name: Dr. Billy Billiken Banner ID: 000123456

Title: Department Chairperson Supervisor: Dr. Iman Charge

Department: Department of Basic Science School: School of Medicine

Position: ☒ SLU Faculty ☐ Adjunct Faculty ☐ Visiting Faculty
☐ SLU Staff ☐ SLU Student ☐ Other: ____

Status: ☒ Full-time ☐ Part-time (% =)

Phone: (314) 977-#### Email: bbilliken@slu.edu

- What is the Nature of the Relationship with the Sponsor?
- What is the Nature of the Research?

SECTION 2 - SPONSOR INFORMATION:

Sponsoring Entity – an organization with which the investigator has a significant financial interest that is directly funding and/or is directly affected by the investigators research activities.

Name of Sponsoring Entity or Entities: Sponsor Name

Name of Related Entity or Entities: ____

Relationship to Sponsoring Entity or Entities: Describe the business relationship between the investigator and the sponsoring entity or entities.

A Consulting Fee was paid by Sponsor Name in exchange for Promotional Talks given during the 2011 calendar year. The compensation I received in connection with my work as a consultant is not related to the research/clinical study that is funded by Sponsor Name currently underway ~~in IRB Protocol #_____~~, titled "Important Study" funded in SLU Account #3-09990. The study beginning date was January 1, 2011 and the expected ending date is ~~December 31, 2012~~.

- Verify that there are no Human Subjects

SECTION 3 – MANAGEMENT PLAN:

Instructions: The investigator will work in cooperation with the Conflict of Interest Committee (COIC) and other interested University officials to reduce, manage, or eliminate any apparent or actual conflict of interest for externally funded research involving the sponsoring entity or entities. The investigator agrees to abide by the policy and procedures set forth in the Saint Louis University Conflict of Interest in Research Policy:

http://www.slu.edu/Documents/provost/research_services/ConflictOfInterestPolicy.pdf

3.1. PROTECTION OF HUMAN SUBJECTS:

If human subjects will be involved in the research activities, describe how the influence of the conflict of interest will be minimized for participants to ensure their safety. Common strategies include formal disclosure during consent and restrictions on the conflicted investigators ability to contact, recruit and/or consent study subjects. There may also be modifications to the analysis and reporting phases of the research.

My research with Sponsor Name does not include any activities with Human Subjects, therefore my conflict of interest will not apply to this section of the Management Plan.

- If Human Subjects are Involved …

3.1. PROTECTION OF HUMAN SUBJECTS:

If human subjects will be involved in the research activities, describe how the influence of the conflict of interest will be minimized for participants to ensure their safety. Common strategies include formal disclosure during consent and restrictions on the conflicted investigators ability to contact, recruit and/or consent study subjects. There may also be modifications to the analysis and reporting phases of the research.

The **eligibility determination process** for human subjects will be performed and signed off on by other un-conflicted study team members, although Dr. Billy Billiken will be available during the eligibility and consent processes to answer questions. One of the sub-investigators will review each subject's eligibility criteria to ensure proper enrollment. The un-conflicted sub-investigators working on this research, who will serve in this eligibility-determining role, are (1) Dr. One and (2) Dr. Two

Consent forms will include the disclosure statement: "Dr. Billy Billiken receives compensation from Sponsor Name, the study sponsor, in connection with his work as a consultant for the sponsor. His work in this capacity is not related to this study." The un-conflicted sub-investigators working on this research, who will serve in this consenting role, are (1) Dr. One and (2) Dr. Two.

Serious Adverse event classification will be performed jointly by un-conflicted sub-investigators and Dr. Billy Billiken. If the conferring investigators require additional input or cannot agree, Dr. Iman Charge (Supervisor) will be consulted for a final determination. The un-conflicted sub-investigators working on this research, who will serve in this adverse event-determining role, are (1) Dr. One and (2) Dr. Two.

3.2. PROTECTION OF PERSONNEL INVOLVED IN SPONSORED RESEARCH:

The investigator must ensure that all personnel, including faculty members and staff directly involved in the design, conduct, and/or the reporting of the research project will be made aware of the associated conflict of interest and the manner in which it will be reduced, managed, or eliminated.

Dr. Billy Billiken is responsible for ensuring that all personnel involved with his research projects are advised regarding his conflict and Management Plan. Personnel that may be impacted include, but are not limited to, co-investigators, students (See Section 3.3), fellows, residents, nurses, and physicians.

In order to meet this responsibility, Dr. Billy Billiken will provide all personnel involved with the conflicted research project a copy of a statement he wrote that includes a description of his involvement with Sponsor Name, the relationship between his research work and the sponsor, and a list of contacts for those who have questions or concerns regarding the conflict. The statement will be reviewed and approved by the Chair of the COIC or her designee. Within 30 days of the implementation of this Management Plan, Dr. Billy Billiken will meet with affected personnel and provide two copies of the written and signed summary. One copy will be retained by the affected person and the other will be signed, dated and returned to Dr. Billy Billiken. The list of individuals who have received and signed the summary will be maintained by Dr. Billy Billiken and reviewed by the Research Compliance Team **bi-annually**.

Investigator's Personal Conflict of Interest Statement

The personal COI Statement will be printed on department letterhead and include the following:

1. date
2. description of the investigator's involvement with the company
3. description of the purpose of the company (the industry in which they operate & the goods or services they provide)
4. description of the relationship between the investigator's professional work (research) at Saint Louis University and the company
5. description of any restrictions placed on the design, conduct and reporting of research connected to the company (refer to section 3.2 of the management plan)

6. description of the protections offered specifically to students, if applicable (refer to Section 3.3 of the management plan)
7. description of the ownership of an intellectual property resulting from research connected to the company
8. impartial contacts for students and staff (the investigator's chairperson, dean, Vice Provost for Research, or Research Compliance, or an anonymous hotline
9. investigator's signature
10. statement of acknowledgement to be signed and dated by the recipient(s)

3.3. PROTECTION OF STUDENTS:

Students, residents, and fellows rely on faculty advice and guidance concerning educational matters within the University (including the nature and direction of research) as well as temporary and career employment opportunities outside the University. Such advice and guidance should always be governed by a student's best interest and should not be made to serve a faculty member's interest in outside commercial and/or professional activities. In addition, protections must be articulated that ensure the protection of student publications.

Dr. Billy Billiken is responsible for providing information on his conflict to students, residents and fellows he supervises in the course of his research. In addition to the process described in Section 3.2, Dr. Billy Billiken will notify students, residents and fellows of their right to bring concerns about the effect of his conflict on their work or progress toward their degree/certification to the Department Chair, the Director of Research Compliance, or the COI Committee.

- Frequency of Compliance Team audits

3.4. PUBLICATIONS AND PRESENTATIONS

Disclosure of the relationship with the sponsoring entity is required in publications and academic presentations. If applicable, protections must be articulated that ensure the protection of student publications.

Dr. Billy Billiken's relationship with Sponsor Name may not restrict publication or presentation. Dr. Billy Billiken must disclose his relationship with Sponsor Name in publications or academic presentations of clinical findings relevant to the sponsor. Disclosures should conform to the requirements of the individual publication or the uniform disclosure guidelines published by Davidoff et al. (JAMA 286:1232-1234, 2001). Dr. Billy Billiken will keep copies of all records related to disclosure in a file that can be requested at any time by the Research Compliance Team. Copies of publications or presentation slides will be maintained by Dr. Billy Billiken and reviewed at __**bi-annually**_____ meetings with the Research Compliance Team.

- Specific details related to Intellectual Property

3.5. INVOLVEMENT OF INTELLECTUAL PROPERTY:

Research activities involving patents, materials, devices, or procedures invented or discovered by faculty members (whether such development took place at Saint Louis University or elsewhere) with the intention of commercial development must be designed and conducted in accordance with Saint Louis University's Intellectual Property Handbook and relevant policies.

Dr. Billy Billiken acknowledges that it is his responsibility to stay informed about the University's policies and procedures regarding intellectual property, and is committed to maintaining his conduct within those parameters. Furthermore, if Dr. Billy Billiken should receive unforeseen compensation directly from Sponsor Name as a result of the intellectual property, Dr. Billy Billiken will submit a revised 2011 Disclosure Form to the Conflict of Interest Committee for their review.

- Affirmative Statement regarding U resources

3.6. USE OF UNIVERSITY RESOURCES:

Faculty members may make reasonable use of their office and office equipment for all activities permitted within the scope of their University employment. University facilities such as laboratories, scientific equipment, University personnel, or students should not be used for activities outside the scope of a faculty member's academic responsibilities if these activities are conducted primarily for the financial benefit of the faculty member or for the benefit of a company or enterprise with which the faculty member is associated. A faculty member who wishes to use University laboratory space for a commercial project must receive prior approval through the Conflict of Interest disclosure process, and must follow other related policies as applicable, such as the Research Facilities Lease Agreement, the Extramural Activities Policy, and the Faculty Manual.

University-owned office equipment, technology (such as the laptop computer), and laboratory resources provided by the University are used for activities permitted within the scope of Dr. Billy Billiken's employment, and Dr. Billy Billiken will not allow them to be used or abused on behalf of any outside interests, including the commercial interests of Sponsor Name.

- Investigator's recognition of COI and related assurances

3.7. OTHER CONSIDERATIONS AND SPECIAL CIRCUMSTANCES:

I am now, as always, willing to comply with University policies and will cooperate completely in trying to eliminate/manage perceived or real conflicts of interest. Should there be any changes in my relationships with the sponsoring company, I will notify the committee and develop or amend my Management Plan as appropriate. Furthermore I will submit my annual COI Disclosure Form to the Office of Responsible Conduct in Research within the prescribed timeframe as a token of my commitment to the University's COI Policies and Procedures.

- Frequency of Compliance Team audits

3.8. REPORTING AND REVIEW OF MANAGEMENT PLAN:

The COIC may require the conflicted investigator to report formally on the status of his compliance with the approved management plan. If so, the COIC will formally review the report and inform the investigator of their findings.

Dr. Billy Billiken will meet with a member of the Research Compliance Team every **six** months to provide updates to the circumstances surrounding the conflict as well as to describe carrying out the terms of the management plan. Violations of the management plan may lead to termination of research privileges and additional sanctions specific to the violation. It is Dr. Billy Billiken's responsibility to notify the COIC if there are any changes in his relationship with Sponsor Name.

- Restate specific roles of all involved
- Name specific months for audit follow-up

SECTION 4 — MANAGEMENT PLAN PARTICIPANTS:

Name	ROLE/RESPONSIBILITIES
Dr. Billy Billiken *Conflicted Investigator*	Dr. Billy Billiken will maintain all documents as outlined in this plan. He will meet with a member of the Research Compliance Team in **March & October** to review the terms of the management plan. He will notify the COIC in writing if there are any changes in his personal financial relationship with any of the sponsoring agencies to his research.
Dr. Iman Charge *Supervisor to the Conflicted Investigator*	The Research Compliance Team will update Dr. Iman Charge regarding progress of the Management Plan. Dr. Iman Charge will intervene if there are questions or concerns that cannot be resolved directly with Dr. Billy Billiken.

SECTION 4 — MANAGEMENT PLAN PARTICIPANTS, Continued:

Name	ROLE/RESPONSIBILITIES
Kathleen Merlo, Director of Research Compliance *Management Plan Oversight*	Ms. Merlo, or a designee (a member of the Research Compliance Team) will meet with Dr. Billy Billiken bi-annually to review the terms of the Management Plan. Ms. Merlo will maintain minutes of the meetings and will maintain a file detailing the monitoring activities associated with this Management Plan.
Conflict of Interest Committee Management Plan Approval and Oversight	The Research Compliance Team will update the Conflict of Interest Committee regarding the progress of the Management Plan, as well as the efforts of the Team to verify the nature of the Plan (Objective, Practical, Enforceable and Verifiable).

SECTION 5 — APPROVAL SIGNATURES:

I agree to abide by the terms and conditions set forth in this management plan to reduce, manage, or eliminate any apparent or actual conflict of interest in research.

Investigator Signature:

_____ ___/___/_____
Date

Department Approval:

_____ ___/___/_____
Signature of Department Chair Date

Institutional Approval:

_____ ___/___/_____
Signature of Dean Date

Conflict of Interest Committee (COIC):

_____ ___/___/_____
Signature of COIC Chair Date

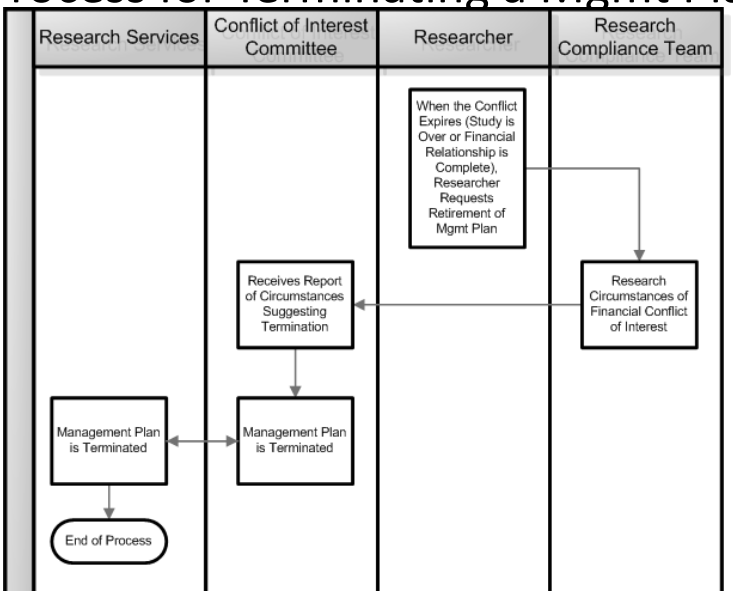
Oversight Process on Mgmt Plan

- Research Compliance Team initiates a review of the Management Plan *periodically* throughout the year
  - Review Current Research
  - Phone Interview
  - Review IRB Documents
  - Review Payroll
  - Review Publications & Presentations

Addendum

- Based on the volume and variety of conflicted studies, we often NAME the CONFLICTED STUDIES inside an Addendum, rather than on the first page of the Mgmt Plan
  - Flexibility to write in new conflicted studies and to exclude terminated studies without substantial change to the Management Plan

Process for Terminating a Mgmt Plan



Formal Sanctions List

Advantages:

- † Clear Consequence
- † Ensures Consistency
- † Predictable
- † Transparent
- † Efficient
- † Supports Compliance

Disadvantages:

- – Requires Support from top management

Formal Sanctions List

I.

- Investigator & research team must complete:
  - an on-line training session on COI
  - a classroom training session on COI
  - A classroom session on Research Ethics
- Require the investigator to present a verbal explanation to the research team members as to the nature of the conflict (to accompany the distribution of the written Personal COI Statement).

II.

- Require the Investigator to:
  - Submit evidence of the date that a significant change occurred when submitting a Revised COI Disclosure Form
  - Submit annual COI Disclosure Form within 14 days of the disclosure period as a gesture of their committed cooperation to the University's COI policies and procedures.
- Require the investigator and chairperson to participate in face-to-face meetings with the Research Compliance staff on a frequent basis.
- Require the researcher to sign statement that they are in compliance with the prescribed Management Plan and that no changes have occurred

Formal Sanctions List

III.

- Require the investigator and chairperson to participate in a face-to-face meeting with Research Compliance staff to personally construct an appropriate Corrective Action Plan (CAP)
- Require the investigator and chairperson to participate in a face-to-face meeting with the Conflict of Interest Committee in Research to discuss the investigator's understanding of the non-compliance and present the CAP
- Require the investigator and chairperson to participate in a face-to-face meeting with the Dean to review the terms of the CAP and demonstrate the researcher's understanding of the consequences of non-compliance.

IV.

- Do not allow any additional research applications
- Do not allow future research with the conflicted entity
- Do not allow any future research
- Freeze the spending on a conflicted grant
- Return the grant proceeds to the sponsor of a conflicted grant
- Terminate the investigator

Thank
You