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**IRB Supplement Form N**

**COI Disclosure Form**

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| **PI Name:**  | **Date:** Click here to enter a date. |
| Protocol Title:  | WMed IRB#: *(for IRB Office only)*  |

Complete this form if the PI, Project Director, or any research team members (including collaborators or consultants) with responsibilities that include design, investigation and conduct, analysis, and reporting of research activities or findings on this study might have a conflict of interest. Submit a separate form for each individual having a potential conflict of interest. The form should be completed by the person with the potential conflict.

1. **Description of Conflict**
	1. **Who has the potential conflict?**

[ ]  Principal Investigator (PI).

[ ]  An individual with a Personal Relationship to the PI.

Specify:

[ ]  Member of the research team.

Specify and describe their role in the research:

[ ]  An individual with a Personal Relationship to a member of the research team.

Specify:

Note: A Personal Relationship includes the spouse, domestic partner, dependent children, individuals living in the same household, and other individuals with a consensual romantic, intimate, or sexual relationship**.**

* 1. **Name of organization or business:**

* 1. **Nature of the relationship:**

[ ]  Has an ownership interest, stock options, or other equity interest in the organizationnoted above greater than 5% of total equity.

[ ]  Received or will receive payments from the organization noted above that exceed $5,000 when aggregated for the Covered Individual and individuals with a Personal Relationship to the Covered Individual.

[ ]  A financial interest in the research with value that exceeds $5,000 when aggregated for the Covered Individual and individuals with a Personal Relationship to the Covered Individual in one year.

[ ]  A proprietary interest in the research, such as a patent, trademark, copyright, or licensing agreement.

[ ]  A proprietary interest in the research other than copyrights and patents without royalties.

[ ]  Serves as an executive or director of the organization noted above.

[ ]  Income from seminars, lectures or teaching engagements sponsored by the organization noted above.

[ ]  Income from service on advisory committees or review panels for the organization noted above.

[ ]  Any compensation whose amount would be affected by the outcome of the research.

[ ]  Travel expenses that are related to a covered person’s institutional responsibilities that are reimbursed or sponsored by a for-profit or non-profit organization, except when the travel paid for by this institution or a U.S. federal, state, or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital or medical center, or a U.S. research institute affiliated with an institution of higher education.

[ ]  A financial interest that requires disclosure to the sponsor or funding source.

[ ]  A financial interest in the research with value that cannot be readily determined.

Specify:

[ ]  Any other financial interest that the investigator believes may interfere with his or her ability to protect participants.

Specify:

* 1. **What is the amount of this financial relationship (amount of equity, annual compensation, etc.)?**

1. **Relationship to the research**
	1. **How is the organization or business noted above related to the research?**

* 1. **Could the financial relationship described above be affected by the outcome of the study?**

[ ]  Yes [ ]  No Explain:

1. **Disclosure & Management**
	1. **Has this financial relationship been previously reported to WMed and if so, has WMed issued a conflict management plan or restrictions or conditions?**

[ ]  Yes [ ]  No

If no, please submit to the institutions Conflict of Interest Committee.

* 1. **If the answer above is yes, has WMed approved a conflict management plan or provided a determination in writing concerning restrictions or conditions?**

[ ]  Yes [ ]  No

If yes, please provide a copy and summarize below:

* 1. **What mechanisms, if any, do you have in place to manage any potential conflict of interest (e.g., outside data analysis, data safety monitoring, blinded trial)?**

* 1. **Is this financial relationship disclosed to subjects?**

[ ]  Yes [ ]  No

If yes, how?