Yale University Human Research Protection Program

500 CH.1 Evaluating Financial and Non-Financial Interests Related to Human Research

Protocol # _____ **Principal Investigator:** _____

Funding Source: _____

Person(s) with Interest: _____

Interest Identified: _____

Relatedness: Definite ___ **Probable** ___ **Possible** ___

IRB Reviewer:_____ **Date of Review:**_____

Study Attributes:

- Number of subjects. [If multi-site, number of sites involved, and whether Yale investigator is overall PI].
- Study design. [Randomized, placebo controlled, open label?]
- Level of risk to subjects.
- Who determines subject eligibility?
- Who obtains consent?
- Who is serving as the data and safety monitoring board or otherwise overseeing integrity of study data and safety of the study?
- Who conducts data analysis?
- Whether disclosure of the interest is in the consent form.

Human Research Protection Considerations:

- Does the protocol-specific interest have the potential to adversely affect the protection of participants in terms of the criteria for IRB approval (e.g., whether, due to the conflict, risks to subjects are made greater, rather than minimized)?
- Do the risks associated with the interest compared to benefits remain reasonable?
- Does the interest permit subject selection to remain equitable and unbiased?
- Should potential research volunteers be informed of the interest?
- Will the interest and the current protocol design have the potential to adversely affect the integrity of the research?

Management plan___ Limiting the researcher's role in the study. Consider, for example, prohibiting recruitment of or obtaining consent from potential research volunteers;

___ Restricting data collection or analysis activities;. ____ Requiring a monitor for the initial consent process with potential research volunteers;

____ Requiring an independent Data and Safety Monitoring Board, or someone external to Yale to oversee the conduct of a study, or evaluate study outcomes or adverse events; and/or

___ Eliminating the conflict either by removing the individual with the conflict from the study or requiring the individual to reduce the interest to a permissible level.

___ None required

Subject Notification

Information on interest included in consent document: Yes ___ Not Required ___