

## BRIDGEPORT HOSPITAL IRB CONFLICT OF INTEREST STATEMENT

*To be completed with every protocol submitted for initial and continuing review and for federally funded protocols by any person regardless of title who is responsible.*

**Principal Investigator:** \_\_\_\_\_ **IRB #** \_\_\_\_\_

In order to protect subjects from financial conflicts of interest or perceived conflicts of interest, promote objectivity in research, and to comply with federal regulations contained at 42 CFR Part 50, Subpart F and 45 CFR Part 94, the IRB requires that potential conflicts be disclosed as required by Hospital policy and that you have completed training as required under any laws or regulations pertaining to your research regarding the disclosure of potential conflicts.\*

If the IRB determines that a conflict exists that could influence the research or jeopardize the well being of subjects, the IRB may require additional information about the conflict or may require that the conflict be resolved before the research is approved. In addition, it may require that the conflict be disclosed to the subject in the Informed Consent Statement or that you take other appropriate action.

If your study involves a Public Health Services prime award or subaward, you should only submit this statement after you have completed the National Institute of Health's Financial Conflict of Interest tutorial (see applicable Hospital policy) or any other training approved by the Hospital and/or required by Hospital policy.

If you or any member of your immediate family (spouse, children, parent, in-laws, and siblings) has a significant financial interest related to your institutional responsibilities on behalf of the Hospital, or if you are paid or reimbursed for travel or make use of sponsored travel related to your institutional responsibilities, or have had such an interest or travel privileges in the twelve (12) months prior to your making this disclosure, , please indicate the following information about the financial interest:

- Yes  No I own equity or have owned intellectual property rights or interests in a company with interests in a drug, medical procedure, technique or device.
- Yes  No I am aware that a faculty member or other employee of the institution owns or has owned equity in a company with interests in a drug, medical procedure, technique or device.
- Yes  No The company or I hold(s) or has held patent rights to inventions created by me or a member of my immediate family (spouse, children, parent, in-laws, and siblings) or by another faculty member or other employee of the Hospital.
- Yes  No I or a member of my immediate family hold(s) or has held a position of senior management officer, or director of a company within the last twelve months with an interest in a drug, medical procedure, technique or device.
- Yes  No I am aware that a faculty member or other employee of the Hospital hold(s) or has held a position of senior management, officer, or director of a company whose drug, procedure, technique, device, or software I am testing.
- Yes  No I am or have been a scientific advisor or consultant to a company described above and I receive(d) honoraria exceeding \$5,000 annually or in the last twelve months.
- Yes  No I am aware that if a device, technique, or procedure involved in the research is marketed, I or a member of my immediate family will get royalty income or other income from the sale of the product or has received such income in the last twelve months.

Yes  No I am aware that if the drug, device, technique, or procedure involved in the research is marketed, another faculty member or other employee of the institution will get royalty income or other income from the sale of the product or has received income in the last twelve months.

Yes  No I have a financial interest greater than \$5,000 in a publicly traded entity, a non-publicly traded entity, or intellectual property rights or I am paid or reimbursed or make use of sponsored travel related to my institutional responsibilities.

Yes  No I have some other financial interest that may appear to conflict with the protection of subjects or which should be disclosed to subjects in order to secure informed consent.

Yes  No I agree to disclose significant financial interests in accordance with the Hospital's policies at least annually during the period of my research and within 30 days of my discovery or acquiring a new significant financial interest.

Please include a separate letter of explanation if there is further information that the IRB should consider.

If I have not checked any of the boxes above, or attached a letter of explanation for consideration by the IRB, my signature below is my representation that my spouse, dependent children and/or I have no financial or other conflict of interest that could adversely affect a subject in this study. I also understand that a violation of the Hospital conflict of interest policies may constitute cause for disciplinary or other administrative action.

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Date

\*Conflict of interest policies required by federal law and regulation are publicly posted on the Hospital's website.

Please include a separate letter of explanation if there is further information that the IRB should consider.