

**PRINCIPAL INVESTIGATOR CONFLICT OF INTEREST DISCLOSURE STATEMENT (v3.0)**

I HAVE READ AND UNDERSTAND THE CHRISTUS RESEARCH FINANCIAL CONFLICT OF INTEREST POLICY

The CHRISTUS Health System Office of the Protection of Research Subjects requires that **each** protocol submitted to the IRB for review must be accompanied by a Conflict of Interest (COI) Disclosure Statement for **each** Investigator who is directly involved in the treatment or evaluation of research subjects in the covered study. COI Disclosure Statements must be completed, signed and submitted with the Initial IRB Application for review to occur.

Principal Investigator: \_\_\_\_\_

Title of Protocol: \_\_\_\_\_

In order to protect subjects from financial conflicts of interest or perceived conflicts of interest, the IRB requires that such potential conflicts be disclosed. 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.

If you or any member of your immediate family (spouse, children, parent, in-laws, and siblings) has a financial interest in either a public or private company whose drug, procedure, technique, device, or software is used or tested in this study, **please indicate by initialing under the appropriate response** to the following:

- | Yes   | No    |  |
|-------|-------|--|
| _____ | _____ | A member of my immediate family or I own equity in the company (stock ownership equal to or greater than 1% or \$5,000, Stock Options, Real Estate, or other ownership interest in any amount) whose drug, procedure, technique, device, or software I am testing. |
| _____ | _____ | The Company currently holds patent rights to inventions created by me or a member of my immediate family (spouse, children, parent, in-laws, and siblings).  |
| _____ | _____ | A member of my immediate family or I hold(s) a position of senior management officer or is a director of the company whose drug, procedure, technique, device, or software I am testing.   |
| _____ | _____ | A member of my immediate family or I am a scientific advisor or consultant to the company and my immediate family member or I receive honoraria exceeding \$5,000 annually.  |
| _____ | _____ | A member of my immediate family or I will get royalty income or other income from the sale of the product if a device, technique, software, or procedure involved in the research is marketed.   |
| _____ | _____ | A member of my immediate family member or I have any 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.  |

Please include a separate letter of explanation if any of the above are checked “yes” and attach appropriate explanatory documents or information.

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If I have NOT checked any of the boxes above, or not attached a letter of explanation for consideration by the IRB, my signature below is my representation that I have NO financial or other conflict of interest that could adversely affect a subject in this study.

I acknowledge that I am required to notify the IRB within 10 business days if a change in my disclosure status occurs.

Signature: \_\_\_\_\_

Date \_\_\_\_\_

**Useful Websites:****OHRP:**

<http://www.hhs.gov/ohrp/>

**FDA:**

<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm>

**HIPAA Privacy Rule:**

<http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html>

**CHRISTUS Health Conflict of Interest Policy:**

[https://christus.service-now.com/MyCHRISTUSLife/knowledge.do?sysparm\\_document\\_key=kb\\_knowledge,4d88e3ae6fe81e00063ec951be3ee42b](https://christus.service-now.com/MyCHRISTUSLife/knowledge.do?sysparm_document_key=kb_knowledge,4d88e3ae6fe81e00063ec951be3ee42b)