**Institutional Review Board**

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[http:www.choa.org/clinicalresearch](http://www.choa.org/clinicalresearch)



# Investigator Financial Disclosure/Conflict of Interest Statement

Investigator is defined as any member of the research staff.

Immediate family is defined as spouse or dependent children.

For **PHS** funded studies: 1) disclosure by **senior key personnel** is required **prior** to submission for funding 2) disclosure is required related to **institutional responsibilities**;

3) disclosure is required for reimbursed or sponsored **travel** related to **institutional**

**responsibilities; and**

4) updates are required with the annual progress report, twelve (12) months after notice of award, or initiation of research, whichever date is earliest.

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| **Title of Proposal:** | |
| **Principal Investigator:** | **Department:** |
| **Telephone:** | **Fax:** |
| **Email:** |  |

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| **1. Does any investigator, staff member, student, or his/her immediate family, individually or in aggregate have any financial interest, including salary, consulting fees, equity, stock options, licensing fees or other compensation related to the research from the sponsor or other entities having a financial interest in intellectual property, product, or service which is the subject of the proposed research?** |
| 🞎 No (go to question 5) 🞎 Yes, specifically: |

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| 1. **Does any investigator, staff member, student, or his/her immediate family have any**   **intellectual property interest in the drug, device, technology or service being studied?** |
| 🞎 No 🞎 Yes, specifically: |

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| **3. Does or will any investigator, staff member, student, or his/her immediate family have any equity or ownership interest (excluding mutual funds)?** |
| 🞎 No 🞎 Yes, specifically: |

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| **4. Does or will any individual receive annual payments including salary, consulting fees, royalty or licensing payments or other payments?** |
| 🞎 No 🞎 Yes, specifically: |

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| **5. Was the drug, device, technology or service involved in this study developed at Children’s?** |
| 🞎 No 🞎 Yes, specifically: |

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| **6. Is the sponsor of this study a Children’s start-up company?** |
| 🞎 Not applicable, no study sponsor (go to question 8) 🞎 No 🞎 Yes |

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| 1. **Is any investigator, staff member, student, or his/her immediate family a director, officer,**   **partner, trustee or employee hold a position of management, in the sponsoring company or agency?** |
| 🞎 No 🞎 Yes, specifically: |

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| **8. Does any investigator, staff member, student, or his/her immediate family have a financial interest that could reasonably appear to affect the design, conduct or reporting of the proposed research activity or has any arrangement been entered into that would affect the compensation or ownership interest?** |
| 🞎 No 🞎 Yes, specifically: |

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| 1. **Are reimbursement, funding or financial interests of any investigator, staff member, student, or**   **his/her immediate family or the Children’s division or medical area involved affected by**  **subject recruitment?** |
| 🞎 No 🞎 Yes, specifically: |

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| 1. **Is any investigator, staff member, student, or his/her immediate family planning to**   **develop any material or innovations from the results of this study that may be subject to copyright or**  **patent (manuscripts submitted to scientific journals excluded)?** |
| 🞎 No 🞎 Yes, specifically: |

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| 1. **If any financial or intellectual property conflicts of interests exist, how will they be minimized in the conduct of this study?** |
| Please describe: |

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| 1. **Signatures of study personnel: By their signatures below, the study personnel certify that either no**   **conflict of interest exists or that a complete listing of all conflict of interests related to the proposed**  **study is provided. All individuals named below further acknowledge their responsibility to disclose any**  **new reportable conflicts of interest annually and/or during the term of this study. The Principal Investigator’s signature also certifies that all individuals requested to make disclosures have been listed below.**  ***For clarity, please coordinate the order of the signature with the order of names provided in Study***  ***Personnel section of the Initial Submission Form. Please also add any additional signature lines as***  ***needed.*** |

1.

Signature of Principal Investigator/ Printed Name Date

Senior Key Personnel

2.

Signature of Investigator or Staff Member Printed Name Date

3.

Signature of Investigator or Staff Member Printed Name Date

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| **Disclosure related to Institutional Responsibilities (if yes, provide details)**  1. Compensation (including travel expenses). Have you or a member of your family received compensation from a for-profit entity for activities such as consulting, expert witness, advisory board membership, and the like?  □ yes □ no  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  2. Equity. Do you or a member of your family own stock or hold stock options with a publicly-traded or privately-owned entity? □ yes □ no  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  3. Role. Do you or a member of your family serve as a director, trustee, officer or other key employee in a for-profit corporation, partnership, business, or other entity outside of the CHOA. □ yes □ no  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  4. Intellectual Property. Do you or a member of your family have rights to and/or receive royalties from intellectual property (including, patents copyrights and trademarks but excluding academic or scholarly works) licensed to and/or owned by a for-profit entity? Do NOT include intellectual property owned or managed by CHOA.  □ yes □ no  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **Travel Reimbursement\***  Purpose of Trip:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Sponsor/Organizer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Destination: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Amount ($): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \*NOT required to disclose travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education |

1.

Signature of Principal Investigator/ Printed Name Date

Senior Key Personnel

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