PRO REVIEWER CHECKLIST

|  |
| --- |
| **GENERAL INFORMATION** |
| **Researcher:** | **Sponsor:**  |
| Study Title:  | Type of Award:  |
| Primary PRO Reviewer:  | Date Reviewed:  |

**A. Guidelines for determining whether a financial interest is related to research**

|  |
| --- |
| **ORI REVIEWER CHECKLIST** |
| **GENERAL** | **COMMENTS** |
| Do any of the entities disclosed receive or provide funding for the research? |  Yes [ ]  | No[ ]  |  |
| Do any of the entities receive or provide materials or data used or generated in the research, or have a collaborative role on the research? |  Yes [ ]  | No[ ]  |   |
| Does the research involve the use of a drug, device or other product manufactured or distributed by a company with which the Investigator has a financial interest? |  Yes [ ]  | No[ ]  |  |
| Would an entity with which the Investigator has a financial interest benefit from receipt of data from the research before it is publicly available? |  Yes [ ]  | No[ ]  |  |
| Does the research involve the use of a drug, device or other product that is directly competitive to a drug, device or product manufactured/distributed by the disclosed entity? |  Yes [ ]  | No[ ]  |  |
| Does the research involve the use or evaluation of the Investigator’s technology or intellectual property? |  Yes [ ]  | No[ ]  |  |
| Does the research involve the use or evaluation of technology developed by or licensed to a disclosed entity? |  Yes [ ]  | No[ ]  |  |
| Does it reasonably appear there is a relationship between the Investigator’s research projects and his/her financial interest? |  Yes [ ]  | No[ ]  | .  |

|  |
| --- |
| **ORI ADMINISTRATIVE COMMENTS AND NOTES FOR THE PRO REVIEWER/COMMITTEE** |
| Brief description of the study  |
| Potential Conflict of Interest:  |
| Background information pertaining to disclosed entity (if applicable):  |
| Other: |

 **B. Guidelines for determining whether a financial interest is also a conflict of interest**

|  |
| --- |
|  Is there a direct and significant relationship between the investigator’s financial interest and the research project? For instance, could the research results be directly impacted by the investigator’s relationship with the company or entity? Or could the value of the entity directly and materially benefit from the research results?  |
| Criteria for PRO Review and Approval: Please review the criteria for PRO approval and list any comments or concerns in the corresponding comment box or in the open space below. Please write recommendations directly to the VC of Research. (Criteria for PRO approval of research in accordance with [45 CFR 46](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/) and [NIH Policy](http://grants.nih.gov/grants/policy/coi/)). |
| **PRO REVIEWER CHECKLIST** | **COMMENTS** |
| 1 | The PRO has the expertise needed to review this financial interest | Yes[ ]  | No[ ]  | N/A[ ]  | *If no, contact ORI staff to arrange consultation with an ad hoc reviewer - ASAP.* |
| 2 | I, the PRO reviewer, have a conflict of interest with this application | Yes[ ]  | No[ ]  | N/A[ ]  | *If yes, contact ORI staff for reassignment - ASAP.* |
| 3 | Could the outcome of the research affect the value, development or marketability of any drugs, devices or other produces manufactured or distributed by an entity with which the Investigator has a financial interest? | Yes [ ]  | No[ ]  | N/A[ ]  |  |
| 4 | Does the Investigator have an incentive to share research results with an entity with which the Investigator has a financial interest before the data is publicly available? | Yes [ ]  | No[ ]  | N/A[ ]  |  |
| 5 | Could the financial interest create a sense of reciprocity in the Investigator? | Yes [ ]  | No[ ]  | N/A[ ]  |  |
| 6 | Is there a relationship between the financial interest and the outcome of the research? (i.e., is an assay developed by the Investigator being tested for efficacy or merely being used in the project?) | Yes [ ]  | No[ ]  | N/A[ ]  |  |
| 7 | Is the investigator in a position to make administrative decisions for the institution with respect to the financial interest or a related project? (i.e., negotiate research agreements, assign or remove staff from the project, assign facilities or other resources toward project, determine reporting or publication timelines, etc.)  | Yes [ ]  | No[ ]  | N/A[ ]  |  |
| 8 | Entity has a valid address and established facilities. | Yes [ ]  | No[ ]  | N/A[ ]  |  |
| 9 | Sponsor’s program supports University-industry relationships (e.g., SBIR, STTR, Discovery). | Yes [ ]  | No[ ]  | N/A[ ]  |  |
| 10 | Other non-conflicted UCR Investigators are involved in the design of the research project. | Yes [ ]  | No[ ]  | N/A[ ]  |  |
| 11 | Other non-conflicted UCR Investigators collect data and perform data analysis. | Yes [ ]  | No[ ]  | N/A[ ]  |  |
| 12 | Other non-conflicted UCR Investigators are involved in the reporting. | Yes [ ]  | No[ ]  | N/A[ ]  |  |
| 13 | Is an invention is related to the research? | Yes [ ]  | No[ ]  | N/A[ ]  |  |
| 14 | Is intellectual property is licensed to Entity? | Yes [ ]  | No[ ]  | N/A[ ]  |  |
| 15 | Is university-owned intellectual property involved? | Yes [ ]  | No[ ]  | N/A[ ]  |  |
| 16 | Consulting agreement acknowledges the Investigator’s University obligation? | Yes [ ]  | No[ ]  | N/A[ ]  |  |
| 17 | Investigator is in a supervisory role over students involved in the proposed research? | Yes [ ]  | No[ ]  | N/A[ ]  |  |
| 18 | Research involves human subjects? | Yes [ ]  | No[ ]  | N/A[ ]  |  |
| 19 | Investigator is involved in collection of data? | Yes [ ]  | No[ ]  | N/A[ ]  |  |
| 20 | Investigator performs data analysis? | Yes [ ]  | No[ ]  | N/A[ ]  |  |
| 21 | Investigator involved in obtaining consent/recruitment? | Yes [ ]  | No[ ]  | N/A[ ]  |  |

|  |
| --- |
| **[PRO REVIEWER COMMENTS](#IRBmemberguide" \o "Write directly to the researcher(s) on behalf of the PRO; Use full sentences and not point form; Be specific by referencing the section of concern; Refer to specific guidelines that researchers may find useful in addressing; Use a friendly, collegial tone) (not included above):**  |
| Additional comments:  |

|  |
| --- |
| **RECOMMENDATIONS** |
| **Reviewer’s Recommendation****To PRO** | [ ]  Approval: Not Financial Conflict of Interest[ ]  Approval: Not Financial Conflict of Interest with recommended research safeguards[ ]  Approval: Financial Conflict of Interest with recommended management plan[ ]  Disapproval: Unmanageable Financial Conflict of Interest |
| **Research Safeguards** | [ ]  Disclose financial interest in company to students in lab[ ]  Assign PRO Oversight Member to the student’s thesis/dissertation committee[ ] Refer students to the Office of the OmBuds: <http://ombudsperson.ucr.edu/about_theoo/about.html>[ ]  Other: |
| **Management of Conflict of Interest (if FCOI exists)** |
| [ ]  Modification of the conflicted individual’s role in the study: [ ]  Removal from collecting data. [ ]  Removal from analyzing data. [ ]  Removal from consenting participants. [ ]  Removal from determining enrollment criteria. [ ]  Prohibited from supervising research team members. [ ]  Removal from role as PI. [ ]  Removal from project completely.[ ]  Disclose financial interest in company to students in lab.[ ]  Appoint an oversight member to ensure the protection of graduate students.[ ]  Add non-conflicted, independent faculty peer (non-junior to disclosing individual) to review data and reports.[ ]  Require independent data analysis (e.g. independent statistician or data safety monitoring board)[ ]  Add non-conflicted, independent faculty peer (non-junior to disclosing individual) to study as co-Investigator.[ ]  Add non-conflicted, independent faculty peer (non-junior to disclosing individual) to study as co-Principal Investigator.[ ]  Reduce or divest equity interests.[ ]  Prohibit individual from receiving any income (as a consultant or honoraria) from Entity for the duration of the project. [ ]  Terminate consulting activities for the duration of the project.[ ]  Resign from management position with the Entity for the duration of the project.[ ]  Create an ad hoc committee to provide additional COI oversight.[ ]  Other:  |