

## **IRB Conflict of Interest & Confidentiality Statement For IRB Members, IRB Staff, Consultants and Approved Visitors**

### **Definitions**

**Professional Conflict of Interest:** Exists when an IRB member/consultant, and/or their immediate family (includes a spouse or domestic partner along with your and your spouse's/domestic partners parent/step-parent, siblings, child or step-child, grandparents and grandchildren):

- is a key member of the research team for any protocol under review. This includes the Principal Investigator, Co-investigator, and Study / Project coordinator and any individual that is listed on a grant application or FDA 1572 form;
- acts as an officer or a director of the sponsor or an agent of the sponsor;
- has a professional interest in a competing protocol;
- acts as a protocol consultant, primary advisor and/or the primary mentor for a student or post doc investigator;
- whose employment or job performance is contingent on successful approval of grants and contracts;
- has an employment supervisory or reporting role to the person whose work the Committee is examining; or has a relationship with an entity that grants the member a no-financial benefit, such as a voluntary professional leadership role;
- has identified themselves for any other reason as having a conflict of interest (e.g., having a close personal or professional association with the submitting investigator).

**Personal Conflict of Interest:** Occurs when an IRB member's or a consultant's immediate family has either financial or professional COI.

**Financial Interest Related to the Research:** means financial interest in the sponsor, product or service being tested, or competitor of the sponsor or product or service being tested.

### **Confidentiality**

I understand that information reviewed and discussed by the LRH IRH may include confidential information that is proprietary to commercial entities and/or involves the privacy rights of individuals.

As an IRB member, IRB staff member or consultant, or approved visitor, I agree to abide by the IRB policies for Conflict of Interest and Confidentiality.

- ☐ I will maintain the confidentiality of all discussions, deliberations, records, and other information related to the function of the IRB.

## **Conflict of Interest**

**Potential sources of conflict of interest that should be reported include, but are not limited include:**

1. Ownership interest, stock options, or other financial interest related to the research.
  - With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds Five Thousand Dollars (\$5,000.00). For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
  - With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds Five Thousand Dollars (\$5,000.00) or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
  - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
  - Hold a position as a director, officer, partner, trustee, or employee or any other position held within the sponsor.
  - Not publicly traded on a stock exchange. (Any ownership in a non-public entity).
  - Value will/may be affected by the outcome of the research.
2. Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
3. Board or executive relationship related to the research, regardless of compensation.

**If I have a conflict of interest as defined above:**

- ☐ I will not participate in the IRB discussion and voting of any research in which I have a conflicting interest as defined above.
- ☐ I will describe the conflict of interest and submit this to the IRB Chair who will determine what steps, if any, are necessary to prevent the conflict of interest from interfering with the IRB review of the research, including interfering with the protection of participants.

**Acknowledged and Agreed:**

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Print Name

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Signature

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Date