

## **CONFLICT OF INTEREST GUIDANCE ON INSTITUTIONAL CONSULTING AGREEMENTS FOR HEALTH SCIENCES INVESTIGATORS**

### **What is an Institutional Consulting Agreement (ICA)?**

An Institutional Consulting Agreement (ICA) is an agreement between the University and an outside entity. The outside entity requires the consulting services of a Health Sciences Faculty member subject matter expert. The consulting services being requested can be for professional services (e.g. medical director, clinical trial oversight, faculty consulting, data management for multi-site studies), clinical services (e.g. nurses, dietitians, research personnel), or educational programs (e.g. CME, preceptorships, community health outreach).

The Health Sciences Office of Business Contracting is the office responsible for negotiating ICAs and can be contacted at [hsbizcontracting@ucsd.edu](mailto:hsbizcontracting@ucsd.edu).

### **What are the benefits to using an ICA rather than a personal consulting agreement?**

1. Transparency and better control over the agreements that faculty sign which will reduce the potential for faculty signing unenforceable or legally questionable consulting agreements.
2. Further protection of potential intellectual property.
3. Activities are performed as part of the course and scope of employment, which may provide liability protection and indemnification for faculty as opposed to personal consulting agreements in which the faculty member assumes personal liability.
4. No personal income is received. All funds are directed through the University with the appropriate controls on expenditures.

**As Principal Investigator (PI), am I required to disclose the ICA with the same outside entity on the 700U disclosure form?** As the PI, you must complete the 700U disclosure prior to the initiation of your project. If human subjects are involved, any key personnel listed in section seven of the UCSD HRPP Facesheet (Other Persons Associated with This Project) that have a financial or other conflict of interest must complete the 700U disclosure prior to the initiation of your project. Per HRPP SOPP 3.8, this policy pertains to interests in business, non-profit and public entities in an area related to the research, where the entity could reasonably appear to affect or be affected by the design, conduct, or reporting of the sponsored project or any arrangement where the amount of compensation will be affected by the outcome of the research. If you have an ICA, it is preferred that the ICA is listed on the 700U disclosure, however it is not required. As an alternative, if the disclosing individual prefers not to disclose the ICA on the 700U disclosure, they may disclose their ICAs via email to the COI Office at [coiforms@ucsd.edu](mailto:coiforms@ucsd.edu) when submitting their 700U disclosure.

### **What are the conflict of interest concerns around ICAs?**

University employees who are responsible for the design, analysis, conduct, or reporting of the results of research performed, including a human subjects protocols, must disclose whether or not they have a financial interest in or association with the sponsor or the company supplying the materials, drugs, or devices for the project. Clinical research, including clinical trials, poses special situations that require close scrutiny. The University is responsible for ensuring that human subjects are fully informed and not placed at additional risk because of financial interests on the part of the investigator(s). The Conflict of Interest Independent Review Committee has concerns about the actual and perceived conflict of interest issues, transparency of the ICAs and management strategy options.

### **What is the role of the Conflict of Interest Independent Review Committee?**

The Conflict of Interest Independent Review Committee is the University's independent substantive review committee appointed by the Chancellor to review financial disclosure statements and relevant features of a research project. It functions as the principal advisory committee to the Chancellor for conflict of interest and determines if a potential, perceived or real conflict of interest exists by virtue of the University employee's financial interests and relationship to the research project. The IRC provides an oversight role and strives to safeguard the interests of the University and its employees, and to ensure compliance with University policies as well as state and federal mandates.

### **Can I remain the PI if I have an ICA for consulting with the same outside entity?**

Generally, investigators who have, or participate in, a privately sponsored clinical study shall not concurrently receive any compensation or equity from the sponsor, including honoraria and consulting fees, during the course of the research project. The PI with an ICA may remain as the PI if there is sufficient separation between the proposed project and the outside consulting activities under the ICA and/or based on the type of clinical trial. Due to the actual and/or potential conflict of interest perception concerns, the PI may not be directly involved in:

1. Subject recruitment\*
2. Subject selection\*
3. Obtaining informed consent\*
4. Informed consent must include a witness signature

\* A Co-Investigator with no consulting or other financial relationship with the sponsor must perform these activities.

### **What type of Clinical Trial allows me to be PI and have an ICA with the same outside entity?**

The criteria for the type of clinical trial must include all of the following:

1. Industry-Initiated Phase II or Phase III clinical trial (including open label and retrospective/observational trials), and
2. Is a multi-site clinical trial, and
3. Has an independent Data and Safety Monitoring Board (DSMB).

**What are the possible Management Strategies?**

If sufficient separation and/or applicable clinical trial does not exist, the management strategies may include:

1. Appoint a PI that does not have a related relationship with the company.
2. Discontinue the ICA during the performance of the study.
3. Appoint a PI for the ICA that does not have a related relationship with the company.
4. Remain as Co-Investigator. May see study subjects at study visits to perform a history and physical, and for potentially some of the study required exams or procedures. May not be involved with subject recruitment, selection, and/or the informed consent process.

Regardless, the Investigator with an actual or potential conflict of interest must disclose the relationship with the outside entity:

1. In publications and presentations of the research results for the sponsored project.
2. In the study's Institutional Review Board (IRB) approved Informed Consent Form.
3. To any University graduate student or post-doctoral scholar working on the project. Depending on the extent of the relationship, the Independent Review Committee may require an appointment of a co-chair.