IRC Management Strategy Options for PCAs and ICAs

Principal Investigator (PI)

Personal Consulting Agreement (PCA)

Is there Sufficient Separation?

Yes

Remain as PI with *Standard Disclosure Requirements

No

Institutional Consulting Agreement (ICA)

Meets the ICA Type of Clinical Trial Criteria?

Yes

Remain as PI with the following management strategies:
1. May not be involved with subject recruitment, subject selection, and/or the informed consent process AND
2. Include Standard Disclosure Requirements

No

Is there Sufficient Separation?

Yes

Remain as PI with the following management strategies:
1. Discontinue consulting activities during the course of the University research project AND
2. Include Standard Disclosure Requirements

No

If Sufficient Separation does NOT exist AND does not meet the Type of Clinical Trial; may NOT be PI for the project, see options.

Criteria for Type of Clinical Trial allowed under ICA:
- Industry-initiated Phase II or III (including open label and retrospective/observational studies)
- Multi-site clinical trial
- Independent Data and Safety Monitoring Board (DSMB)

Otherwise Sufficient Separation must exist:
- The consulting activities are NOT directly related to the proposed clinical trial/research and the results could NOT be beneficial to the company OR
- The research does NOT involve the clinical evaluation of the company's drug, device, vaccine or procedure in human subjects

Standard Disclosure Requirements:
The Standard Disclosure Requirement of the investigator's relationship with the company is included:
- In publications and presentations of the results of this research
- In the study's IRB approved informed consent form, if applicable
- To the study team, including any UCSD students working on the project (graduate students and post-doctoral scholars)

Another option:
Become a Co-I and assign a new PI that does not have a financial interest.
As Co-I, permitted to consult with the following management strategies:
1. May not be involved with subject recruitment, subject selection, and/or the informed consent process AND
2. Include Standard Disclosure Requirements

The Investigator may select one of these options:
- Appoint a PI for the ICA that does not have a related relationship with the company.
- Discontinue the ICA during the study.
- Appoint a PI on the research project that does not have a related relationship with the company and can remain as Co-I. As Co-I, may NOT be involved with subject recruitment, subject selection, and/or the informed consent process AND include Standard Disclosure Requirements.

December 2018
**IRC Management Strategy Options for PCAs and ICAs**

**Co-Investigator**

**Personal Consulting Agreement (PCA)**

- **Is there Sufficient Separation?**
  - **Yes**
    - Remain as Co-Investigator with Standard Disclosure Requirements
  - **No**
    - Another option: Not be involved in the project at the University

**Institutional Consulting Agreement (ICA)**

- **Meets the ICA Type of Clinical Trial Criteria?**
  - **Yes**
    - Remain as Co-Investigator with the following management strategies:
      1. May **NOT** be directly involved in subject recruitment, subject selection, and/or the informed consent process **AND**
      2. Include Standard Disclosure Requirements
  - **No**
    - **Is there Sufficient Separation?**
      - **Yes**
        - Remain as Co-Investigator with Standard Disclosure Requirements
      - **No**
        - Remain as Co-Investigator with the following management strategies:
          1. May **NOT** be involved with subject recruitment, subject selection, and/or the informed consent process **AND**
          2. Include Standard Disclosure Requirements

---

**Criteria for Type of Clinical Trial allowed under ICA:**
- Industry-Initiated Phase II or III (including open label and retrospective/observational studies)
- Multi-site clinical trial
- Independent Data and Safety Monitoring Board (DSMB)

Otherwise **Sufficient Separation** must exist:
- The consulting activities are **NOT** directly related to the proposed clinical trial/research and the results could **NOT** be beneficial to the company OR
- The research does **NOT** involves the clinical evaluation of the company’s drug, device, vaccine or procedure in human subjects

**Standard Disclosure Requirements:**
The Standard Disclosure Requirement of the investigator’s relationship with the company is included:
- In publications and presentations of the results of this research
- In the study’s IRB approved informed consent form, if applicable
- To the study team, including any UCSD students working on the project (graduate students and post-doctoral scholars)

---

December 2018