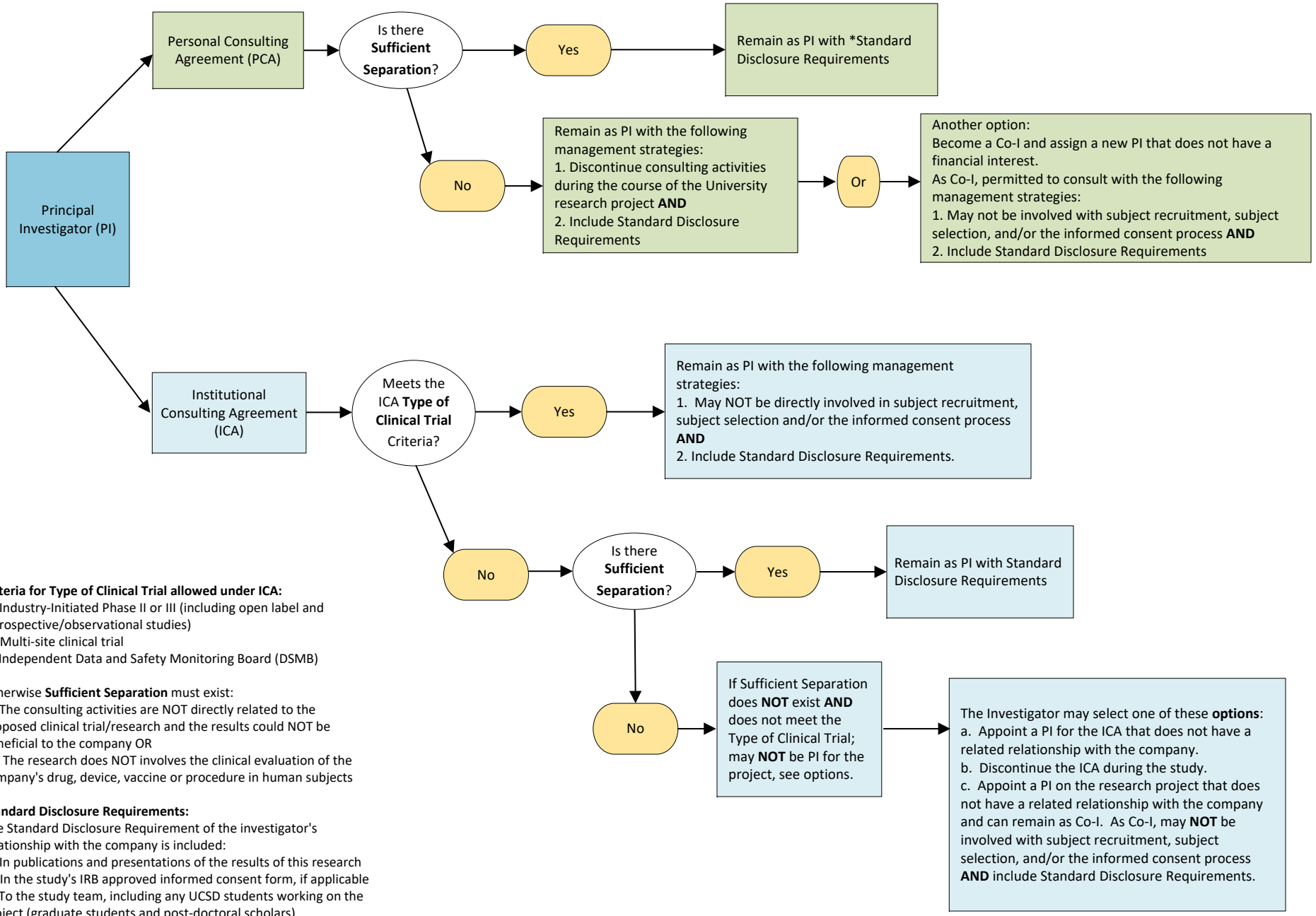
IRC Management Strategy Options for PCAs and ICAs
Principal Investigator



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

Otherwise **Sufficient Separation** must exist:
a. The consulting activities are NOT directly related to the proposed clinical trial/research and the results could NOT be beneficial to the company OR
b. 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:
a. In publications and presentations of the results of this research
b. In the study's IRB approved informed consent form, if applicable
c. To the study team, including any UCSD students working on the project (graduate students and post-doctoral scholars)

December 2018

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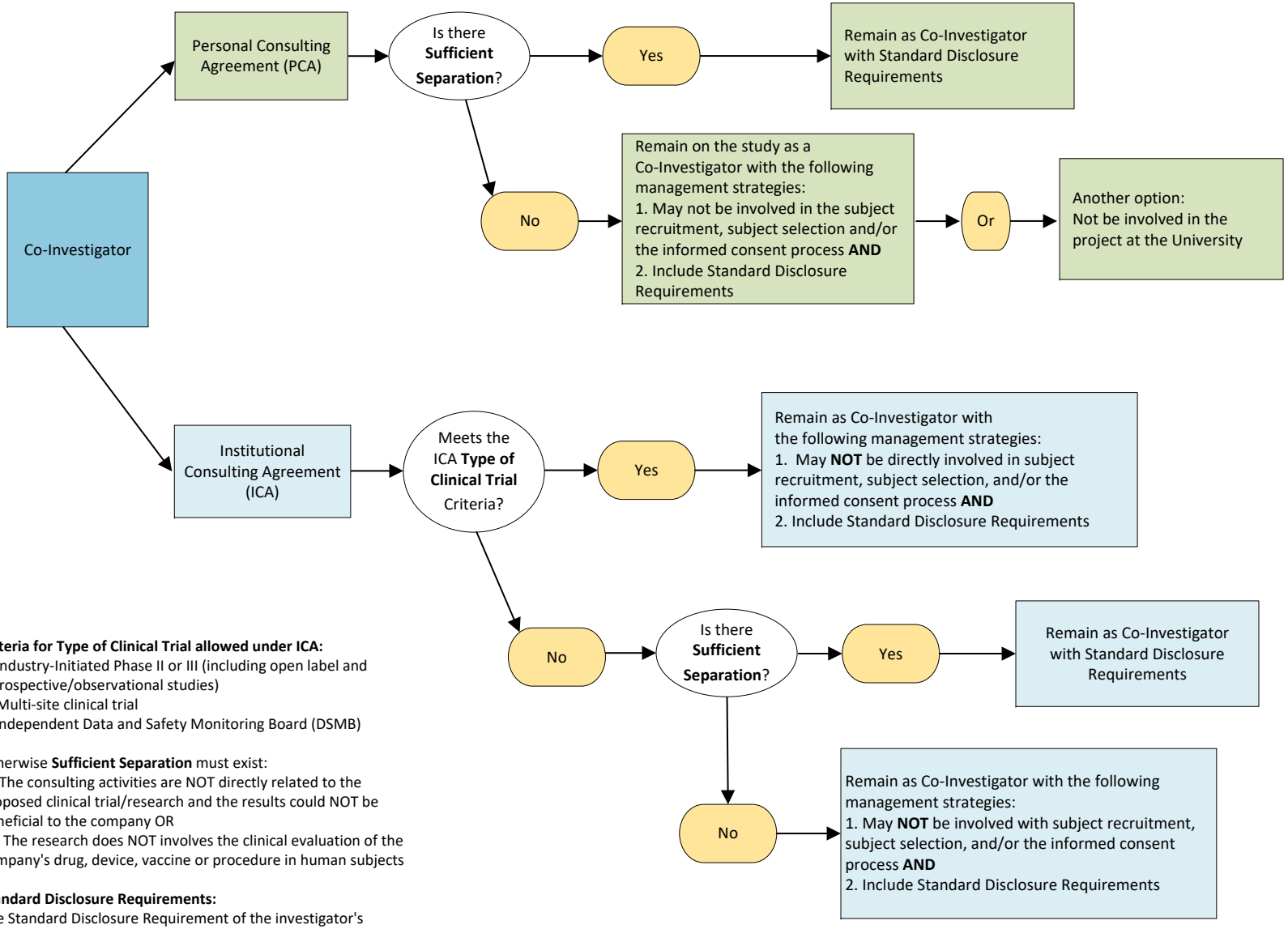
Co-Investigator



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