

CATEGORIES	INVESTIGATOR-INITIATED	INDUSTRY-INITIATED
1. Protocol	<p>a) Protocol authored by a UCSD Investigator within the course and scope of his/her University employment; or</p> <p>b) A UCSD Investigator within the course and scope of his/her University employment jointly with an employee of another entity (e.g. an employee of another non-profit institution, an employee of the company funding the study, etc.)</p>	<p>a) Protocol is authored by a non-UC employee (i.e. the company's employee or an employee of an outside university or institution), or</p> <p>b) A University investigator under a personal consulting agreement and without use of University facilities in accordance with UC policies</p>
2. Indirect Cost	26% Clinical Trial IDC (assessed on all costs). If the trial is funded by a non-profit, state, or government agency, contact OCGA for additional information.	26% Clinical Trial IDC (assessed on all costs). Contact Clinical Trial Administrative Services with any questions.
3. Funding Source	Investigator-Initiated Clinical Trials are generally funded by a for-profit, non-profit, state, or federal agency.	A for-profit entity <i>must</i> be the source of funding for an Industry-Initiated Clinical Trial.
4. Payment	Although the actual payment schedule is subject to negotiation with the company, the Principal Investigator and departmental administrators should develop a suggested payment schedule that is based upon the spending pattern anticipated for the study. The initial payment should include non-refundable start-up costs, as appropriate. Subsequent payments may be due quarterly, or based on subject enrollment. The University may not underwrite expenses for the company, and reimbursement should remain current with expenditures throughout the life of the study.	Although the actual payment schedule is subject to negotiation with the sponsor, the Principal Investigator and departmental administrators should develop a suggested payment schedule that is based upon the spending pattern anticipated for the study. The initial payment should include non-refundable start-up costs, as appropriate. Subsequent payments may be due quarterly, or based on subject enrollment. The University should not underwrite expenses for the sponsor, and reimbursement should remain current with expenditures throughout the life of the study.
5. FDA Phase	In general, Investigator-Initiated Clinical Trials are either Phase I or Phase II Trials and may be multi-site studies.	In general, Industry-Initiated Clinical Trials may include Phase I through IV and are usually multi-site studies.
6. Investigational New Drug (IND)	The FDA form 1571 is completed by the Principal Investigator who takes responsibility for and initiates the clinical investigation. Additional information, forms, regulations, and guidance is available at http://www.fda.gov/cder , or Forms may be accessed directly at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html	The FDA form 1571 is completed by the industry sponsor who takes responsibility for and initiates the clinical investigation.
7. Publication	<p>a) The University retains the right to publish the results of the Clinical Trial consistent with University policy.</p> <p>b) The Principal Investigator is responsible for registering the trial for publication.</p>	<p>a) The University retains the right to publish the results of the Clinical Trial consistent with University policy.</p> <p>b) The Principal Investigator coordinates with the industry sponsor to determine who will assume responsibility for registering the trial so the results may be published.</p>

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8. Intellectual Property	The University retains all rights to inventions developed under the Study. If the funding source for the Clinical Trial is a for-profit entity, the entity will be granted the first right to negotiate for a license to commercialize such invention. If funding source is a non-profit entity, the non-profit entity will be granted certain non-commercial rights to the invention.	In general, the industry sponsor will own any patentable inventions developed in the direct performance of the protocol.
9. Data	<p>a) The company receives a summary report of the results of the trial, and may receive case report forms, as appropriate. The report may be used by the company for any purpose, subject to the University's intellectual property and publication rights.</p> <p>b) Since the company funding the trial is not the regulatory "sponsor" as the term is defined in the Code of Federal Regulations 21CFR50, the company may not access medical records or other patient identifying information unless a revised authorization specific to the study, and which complies with CMIA requirements is obtained from the subject.</p>	<p>a) The industry sponsor owns the completed case report forms and compilation of data expressed therein that is developed under the trial, and any deliverables required under the protocol. However, the University retains the right to use the case report forms and results for publication, educational and research purposes.</p> <p>b) The industry sponsor may receive and use de-identified clinical trial specimens (blood samples, x-rays, etc.).</p> <p>c) The University retains ownership and unrestricted use of original "raw" data including clinical trial specimens. The industry sponsor may have access to, raw data for FDA inspection/monitoring.</p> <p>d) The industry sponsor may access, but not copy, subjects' medical records containing individual identifiable patient information for the limited purpose of auditing data quality and monitoring the study as required under FDA regulations. The disclosure is allowed under HIPAA, however, such disclosure is not allowed under CMIA without subject's authorization.</p>
10. Subject Injury	Except for injury attributable to the manufacture of the study drug, the University assumes responsibility for any injury directly resulting from the subject's participation. The University will provide medical treatment for any such injuries. It is unacceptable to require billing of third party insurance companies in lieu of recovery of such costs. Neither is it appropriate to restrict participation of subjects based on medical insurance coverage status or the subject's ability to pay.	The industry sponsor is responsible for any injury directly resulting from a subject's participation in the trial, or injuries resulting from the study drug, or the placebo, or protocol procedures. The industry sponsor will reimburse the University for the costs of medical treatment for such injuries. It is unacceptable to require billing of third party insurance companies in lieu of recovery of such costs. Neither is it appropriate to restrict participation of subjects based on medical insurance coverage status or the subject's ability to pay.
11. Required Forms	<p>a) Request for Extramural Support (RES Form)</p> <p>b) 700-U Conflict of Interest Form completed for the PI and Co-PI</p> <p>c) Statement of Work (i.e. protocol)</p> <p>d) Budget 26% (Total Direct Costs) IDC. The budget includes any sub sites participating in the study.</p> <p>e) HIPAA Authorization</p> <p>f) Application for Institutional Research Bulk Account</p>	<p>a) Clinical Trial Agreement Request</p> <p>b) 700-U Conflict of Interest Form completed for the PI and Co-PI</p> <p>c) Budget 26% (Total Direct Costs) IDC. The budget includes any sub sites participating in the study.</p> <p>d) HIPAA Authorization</p> <p>e) Application for Institutional Research Bulk Account</p> <p>f) Clinical Trial Agreement Request Addendum</p>
12. Authorized Administrative Office	Investigator-Initiated Clinical Trials are processed and negotiated by the Office of Contract & Grant Administration. Please contact Carroll Ekberg at caekberg@ucsd.edu or at (858) 534-9884 with any questions, MC 0934	Industry-Initiated Clinical trials are processed and negotiated by the Clinical Trial Administrative Services and Research Compliance Office. Please contact Gail Zydelski at gzydelwski@ucsd.edu, or at (858) 534-1021 with any questions, MC 0706