Univ Calif Dos + Don'ts

CONFIDENTIALITY

DON'T	DO
P.I. separately sign as individual	University sign, terms supercede
Require written agreements with employees	Employees are "bound", "similarly bound"
Mix confidential information with case reports/research results in one definition	Distinct from case reports/research
All information provided by sponsor	"Identified as such", " marked as such or reduced to writing within 30 days of oral disclosure" (See Reader, pp. 15-19).
Sponsor refuses to mark	"Reasonable person would conclude is proprietary and confidential property of Sponsor" Define as "proprietary", "trade secret", and "privileged" (legal definition requires marking)
The Agreement Itself	Attachments, such as Protocol, Budget, or Investigator's Brochure (See Reader, pp. 20-23)
No Time Limit	Prefer 7-year time limit. OK with no time limit if very narrow definition
Omit Carve-outs A, B, C, D	Standard Carve-outs A. Prior known B. Lawfully from third party (to the best of its knowledge) C. Comes into public domain D. Legally required court proceeding E. Independently developed F. Need to be released to treat a subject.
Subject bound by confidentiality; Informed Consent is confidential	

PUBLICATION

DON'T	DO
Sponsor "Approve" Publication	"Review"
"Confidential Information" definition so broad as to "gut" publication (e.g. research results owned by sponsor and are confidential)	Differentiate between confidential information provided by sponsor, and research results
Open-ended period for review and publication delay	Prefer 30 day review, and 60 day delay to file patents (90 days total; ok if 45/45, or other combination); 120 day total delay is maximum, without campus approval under publication policy
Prohibit publication under multi-site publication (i.e. Unqualified: University won't publish results until after the multi-center publication)	Establish point at which UC can publish, in event no multi-site publication. Standard is 12 months after study completion/data base lock; sometimes allow 18 months (rare exception, for NIH complex cooperative groups, allow 24 months; not done for industry projects)

Source Documents:

Contract and Grant Manual, Section 1-400, Publication Policy and Guidelines on Rights to Results of Extramural Projects or Programs
http://www.ucop.edu/raohome/cgmanual/chap01.html#1-400

Guidelines on University--Industry Relations, Guideline 2., Freedom to Publish
http://www.ucop.edu/raohome/cgmemos/89-20.html

California Senate Concurrent Resolution No. 66, "Academic Research: "gag clauses"
http://www.ucop.edu/raohome/cgmemos/let96-05.html

Wall Street Journal Article: "How a Drug Firm Paid for University Study, then Undermined It" (the Betty Dong, UCSF, thyroid study), OTT Information Letter, April 25, 1996

INDEMNIFICATION

(See Reader, pp. 24-26)

Regents Standing Order 104, Duties of the President, Section (dd)(9): "except that specific authorization by resolution of the Board shall be required for documents which involve or which are: (9) Agreements by which the University assumes liability for conduct of persons other than University officers, agents, employees, students, invitees, and guests." http://www.ucop.edu/regents/bylaws/so1004.html

DON'T	DO
Omit "defend"	"Indemnify, defend, and hold-harmless"
Limit to claims from "study subjects"	Claims by "any person"
Limit to "medical injury" or "physical injury"	Injury, by definition, includes property damage (unless the qualifier "medical" or other is added). Complete phrase "injury (including death) to any person, or damage to property" is good, but not essential, as long as language covers "any injury"
Limit to injury caused by study drug	"arising out of or connected with performance of the Study" is preferred. Can also use phrase "alleged to have been caused or contributed to by any substance or procedure administered in accordance with the Protocol"
Qualifications/Conditions, such as "compliance with all laws and regulations" or "follow the Protocol"	Create nexus between the injury and non-compliance: i.e. injuries resulting from failure to follow all laws, or failure to follow Protocol
Qualification/Condition: Sponsor notified within 10 days of any complaint or injury relating to any loss subject to the indemnification.	Eliminate these as conditions of indemnification, and make them contractual duties. Prefer "prompt" notice; after receipt "by UC's Office of General Counsel"; if accept # of days limit as condition, qualify with "unless failure to notify within this time period does not materially prejudice Sponsor's defense of the claim."
Limit to "direct damages"; expressly exclude "indirect and consequential" damages	Cover all claims and damages; let the court decide if indirect or consequential damages are awarded
Time Limit on Indemnification/Doesn't Survive	Must Survive termination/ No Time Limit on Claims
Unqualified exceptions (injuries caused by University negligence, failure to follow protocol, etc.)	"to the extent" caused by can also add qualifier at end "but only in proportion to and to the extent that"
Absolute Right to Settle Claims	"provided, however, Sponsor shall not settle any claims or suits with an admission of fault or wrongdoing on the part of University without University's prior written consent [,which will not be unreasonably withheld].

OWNERSHIP OF RESULTS

Note: Property Law Governs; data or ideas cannot be owned; it is the tangible expression that is owned (See Reader, pp. 15-19)

DON'T	DO
All Data or information generated	Completed Case Report Forms (CRF) Deliverables required under the Protocol Compilation of Data as expressed in CRFs Define "Clinical Trial Results"
Sponsor owns Copyright, ideas, know-how	Limit to above (CRF, Clinical Trial Results)
Preclude use by University	Right to use the CRFs/Clinical Trial Results to Prepare Publications Optional to include use in future university research and education (not necessary if narrow definition)
Limits on use of specimens, biological material	Specimens delivered to sponsor
Sponsor owns raw data, restrict use of raw data to internal, non-commercial research	Access to raw data for FDA inspection/ monitoring; no restrictions on future use
If agreement terms might imply otherwise	Affirmative statement of University ownership & unrestricted use of raw data

Source Documents:

University Regulation No. 4, Special Services to Individuals and Organizations, Section II. 5 ("Notebooks and other original records of the research are the property of the University.")
http://www.ucop.edu/raohome/cgmanual/chap01.html#1-320

Contract and Grant Manual, Section 1-400, Publication Policy and Guidelines on Rights to Results of Extramural Projects or Programs
http://www.ucop.edu/raohome/cgmanual/chap01.html#1-400

Intellectual Property and Data Restrictions in NIH Agreements
http://patron.ucop.edu/ottmemos/docs/ott99-05.html

I.P. RIGHTS/PATENT RIGHTS ·INVENTIONS

See OTT Memo 96-3 at http://patron.ucop.edu/ottmemos/docs/ott96-03.html

DON'T	DO
No nexus between rights and project	In the performance of the trial
All inventions "during period of the agreement"	During the conduct (or performance) of the trial
"Arising from" or "Resulting from" trial	Inventions that necessarily incorporates study drug, including new use, dosage.
Conceived or reduced to practice	Made in direct performance; Made in performance less preferable, though great if adds "that necessarily incorporates" study drug; Conceived in performance not preferable, but can be done (see Lilly) Note – this last option must be used carefully and only with other limitations, such as: limiting to conceptions UC is aware of in a reasonable time frame, e.g., during the trial (this prevents a reach to conceptions UC becomes aware of at some future time); a time limit on the option to negotiate is critical; may want to address future reduction to practice.
Rights to "kitchen sink": know-how, trade secrets, ideas, etc.	Limit to patentable inventions, patentable discoveries; sometimes omitting the kitchen sink and leaving the word "inventions" will work; could try inserting the words "that could be claimed in a patent application" at the end of the "kitchen sink."; always delete "data" and "know how"
Irrevocably grants, hereby grants, clinical trial agreement becomes a license*	Time-limited right to negotiate a license
Option to acquire, no mention of terms such as diligence	Option to Negotiate (need not outline terms, as long as context makes clear that will have terms)
Right to sub-license under non-exclusive	Under non-exclusive, sub-license sponsor's subsidiaries, not affiliates. (A broad right to sublicense under a non-exclusive puts them in direct competition with UC in finding licensees)
Royalty rate based on respective contribution.	Royalty based on respective intellectual contribution is OK
Unlimited option period; no time frame	Reference to "time-limited" OK; Better to spell out. Maximum 180 days total "Election": 30/60 days preferred; 90 max "Negotiation": 90 to 120 days
Silence on patent costs	Prefer: specify duty to reimburse patent expenses
Prosecute patent; grant of power of attorney to sponsor	Advise/consult on, but not control. (Note, only General Counsel can permit others to control)

*Contract and Grant Officers do not have a delegation of authority to enter into license agreements

SUBJECT INJURY

(See Reader, pp. 8-14)

DON'T	DO
Limit to injury from study drug; limit to "research" procedure(s)	Any injury directly resulting from participation in the study; or injuries resulting from study drug, placebo, or protocol procedure(s)
Exclude portions of protocol, or "standard of care", or "procedures designed to benefit the subject directly"	Same as above; Can mention that injury directly resulting does not include natural progression of the disease or underlying medical conditions
Restrict to "immediate care" or "emergency care"	"medical treatment reasonably necessary"
Require 3rd party billing; "unless covered by subject's medical insurance"; first bill insurance	No mention; Can affirmatively state that University will not secure reimbursement from medical insurance for costs reimbursed by sponsor.
Create obligation between sponsor and subject	Obligation to provide medical care for injury or reimburse subject for cost of such treatment is a duty between UC and subject; contract with sponsor requires sponsor to reimburse UC for such costs.
Sponsor has no other obligation to subject or to UC	Qualify with "Except under indemnity provision," Sponsor may well have to pay for lost wages, rehabilitation, pain & suffering, etc., depending on whether the injured subject brings a suit for damages.

UC Policy for Medical Treatment of Human Subjects for Injuries Resulting from Participation in Research (January 19, 1979)
http://www.ucop.edu/raohome/cgmemos/86-21.html

Cover Letter: "I am issuing the attached University policy which sets forth the scope and extent of medical care the University will provide to human subjects who suffer an injury as a result of participation in an authorized University activity. . . The immediate impetus for this revision is a new Federal regulation, effective January 2, 1979, which amends the definition of informed consent to require advising prospective subjects as to whether medical treatment or compensation for physical injuries resulting from participation in biomedical and behavioral research is available and, if so, what it consists of, and where further information about it may be obtained. . .The attached policy provides information you will need for responding to inquiries. The decision on an appropriate fund source with respect to a claim will be made, as is usual, on a case by case basis."

Policy: "The University of California will provide to any injured subject any and all medical treatment reasonably necessary for any injury or illness which a human subject suffers as a direct result of participation in an authorized University activity covered by University policy on the protection of human subjects in research or reimburse the subject for the costs of such treatment [,except when the injury or illness is a consequence of a medical research procedure which is designed to benefit the subject directly]."

OTHER

DON'T	DO
Audit financials	Audit/Access to source documents, medical records, source documentation of medical procedures
Assure compliance with FDA-COI rules (Under 21CFR54, it is the responsibility of the applicant who submits a marketing application for FDA approval)	Prefer affirmative statement: "Investigator will submit" Can agree: "University will assist company in securing" (Note: UC Policy on Disclosure of Financial Interest in Private Sponsors of Research, does not satisfy FDA regulatory requirements)(See Reader, pp.35-36) http://www.ucop.edu/acadadv/acadpers/apm/s1-028.html
Represent/Assure that UC and all its employees have never been debarred under Section 306(a) or 306(b) of the Generic Drug Enforcement Act of 1992	Certify that UC is not been debarred and that none of the employees providing services under the Study has been debarred (See Reader, pp. 33-34) http://www.fda.gov/ora/compliance_ref/debar/default.htm for debarment list http://www.fda.gov/cder/guidance/index.htm for FDA Guidance for Industry on "Submitting Debarment Certification Statement" (PDF file under Procedural (Draft) Section of Guidance)
PI separate party to the agreement	"Read and Acknowledged"
PI "agrees"	Use active voice: PI "will"
Warrant (represents is same as warrants)	Use active voice (e.g. UC is not debarred, does not use, etc); "asserts" or "certifies" OK
Prohibits any use of sponsor's name	OK to restrict use of name in publicity or promotion; UC lists name of sponsor and each award in publicly available awards database.
Omit indemnification or subject injury from "survivor" clause	Not necessary to have survivor clause in agreement; if have, then indemnification and subject injury must be included.

INVESTIGATOR INITIATED
And (DRUG ONLY) STUDIES
(usually our PI authors the protocol, initiates the request to industry)

UC	**Sponsor-Adopted**
Covers some cost of study	Covers all cost
Assumes liability	Assumes all liability
Assumes subject injury	Assumes subject injury
Keeps IP (license option for royalty bearing)	With approval of PI, technology transfer and equity: Okay to give IP
Keeps Data and CRFs	Sponsor gets the CRFs
Narrative Report of Outcomes to Sponsor	Usually no narrative report, only CRFs
Research IDC %	Clinical Trial IDC %