

Request for OTM Review

Type of Agreement:

Please attach as applicable: SOW Protocol MTA Intake Form Relevant Correspondence

UCSF Lead Investigator(s):

Are they HHMI/VA/PICI Investigators?

Other Parties to this agreement are:

Is this a subaward?

Has UCSF executed any prior agreements with the sponsor?

Has another UC campus executed this type of agreement with the sponsor?

What is the urgency, if any, associated with this negotiation?

What is the project's funding source(s)?

The agreement contains the following non-standard Intellectual Property terms that require OTM review (please list):

Do any of the non-standard terms constitute a policy exception?

If yes, please list:

Have you already contacted RPAC regarding an exception?

According to the PI, what is the likelihood of a novel idea or intellectual property arising from their participation in this project?

Section I. Inventions. Invention terms can be found at Section .

For each party who seeks problematic invention rights and for each problematic invention right sought:

- Party(s) seeking invention rights:
- Type of invention rights desired (e.g., assignment, exclusive license, non-exclusive license):
 - Outright/present (“hereby grants/assigns”) or future (“shall grant/assign”)?
 - Is the language “in the box” (i.e., “conceived and reduced to practice in the performance of the study”, “made in the performance of the study”)?
 - If not “in the box”, please describe the problematic language.

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- Is the University obligated to confer rights to unpatentable subject matter (i.e., mentions “unpatentable”, includes more than just inventions and discoveries)?
 - If yes, please describe:
- Are IP rights tied to Confidential Information?
 - If yes, Confidential Information can be found at **Section**
 - If yes, identify any non-standard terms with respect to Confidential Information.
- Is there a penalty clause?
 - If yes, penalty clause is located at **Section**
 - If yes, summarize the penalty clause:
- Are the parties seeking patent rights paying for patent prosecution costs?
- Does UC have the right, but not the obligation, to file patent applications on all inventions it continues to own?
 - If no, please describe:

Section II. Clinical Studies.

Is the sponsor fully funding the Study? (include all sources of funding for study-required procedures and administration costs, even if UC)

Did UCSF investigators contribute to authoring the protocol?

If yes, to what extent?

Does the study test any drug, device or biological?

If yes, for each product being tested under the study, identify:

- Name of the product:
- Company who owns rights to or who otherwise markets the product:
- Is the product being provided to the University at no cost?
 - If yes (at no cost), who is providing the product?
- FDA approved?
 - If yes (FDA approved), for what use?
 - If yes, is the product being studied for an FDA approved or unapproved/off-label use:
 - If being used for an unapproved/off-label use, identify use:
 - If yes, does the Investigator use the product in clinical care?
- For sponsor-initiated clinical studies:
 - If a party seeks ownership of inventions, does the study/agreement meet all the requirements of [14-01](#)?

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- If no, what requirements are not satisfied?
- Subject injury provision can be found at **Section**

Section III. MTAs. Will this Material be used in research projects that have other funding sources?

Section IV. Data & Research Results.

Provisions governing ownership and University use of data can be found at Section(s)
Any non-standard terms governing the University's ownership of, or rights to use data/research results? If so, please describe.

Any other problematic terms? Provide Section of Agreement and summary of problem (e.g., confidentiality of inventions or agreement, publication, patent prosecution, limitations on use or collection of biological samples.)

Please include a copy of the most recent agreement (and, protocol/SOW if applicable) with this form. If redlines are unclear, please paste clean text version of the language sponsor requires UCSF to accept here: