

ANNOTATED SPONSORED RESEARCH AGREEMENT

SPONSORED RESEARCH AGREEMENT	COMMENTS
<p>This Agreement is between INSTITUTION (“Institution”), an institution of higher education having corporate powers under the laws of the State of California [1], and COMPANY INC. (“Company”, or “Sponsor”), a corporation having a principal place of business at _____.</p>	<p>[1] Most, if not all, universities and research organizations have their own form agreement covering their sponsored research. You will almost always be working from the institution’s form. Note that if the institution is a Federal Laboratory (e.g. a Department of Energy National Laboratory, such as Argonne National Laboratory, Lawrence Berkeley National Laboratory, etc.) the contractual regime will be quite different, depending on whether the “Company,” or Sponsor, chooses a sponsored research agreement (now termed a “Strategic Partnership Project Agreement”) or a Cooperative Research Agreement (CRADA).</p>
<p>[2] Agreement Number: Research Program Title: Study of HFF as a potential therapy for AKH Principal Investigator: (“Principal investigator”) Effective Date (“Effective Date”) End Date: (“End Date”) Cost: (“Cost”) Payment schedule: [3]</p>	<p>[2] This section is for administrative purposes. Be sure that the correct Principal Investigator (PI) (or co-PI’s) are identified. The term PI is commonly used in governmental grants (e.g. NIH) grants. The PI is responsible for preparation and conduct of the research grant.</p> <p>[3] In a complicated agreement, a separate definitions section could be included near the beginning of the agreement.</p>
<p>1.1 Performance of the Research Program. Institution will use reasonable efforts to perform the Research Program, described in Exhibit A, which is incorporated and made part of this Agreement. [4]</p>	<p>[4] Exhibit A, the statement of work, will contain a detailed description of personnel, resources, time, and budget for the project. The Institution typically will not guarantee specific results, and the Research Program often will be conducted only on a reasonable efforts basis.</p>
<p>1.2 Objectives. The performance of the Research Program is of mutual interest to Company and Institution, and is consistent with the instructional, scholarship, and research objectives of Institution as a nonprofit, tax-exempt [5], educational institution. This Agreement does not limit the freedom of individuals participating in this Research Program to engage in any other research.</p>	<p>[5] Institutions generally do not want to undertake product testing or development as opposed to research. A different form is usually used for clinical trial agreements. The institution will want to publish any publishable results and typically will not agree to forego competing projects. See Section 4 for more information about publication.</p>
<p>1.3 Principal Investigator [6], [7]. The Principal Investigator will be responsible for</p>	<p>[6] If the Principal Investigator is also a consultant to the Company, he or she cannot use</p>

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<p>performance and supervision of the Research Program. [8]</p>	<p>the institution for consulting purposes. Academics usually, but not always, understand this.</p> <p>[7] In the event that the PI is also a consultant to the Company, it is very important to clearly demarcate intellectual property developed by the consultant (alone or in collaboration with others) as separate from intellectual property developed under the Sponsored Research Agreement (SRA). This can be written as a clause in section 2.11.</p> <p>[8] Possible addition:</p> <p>In the event that the Principal Investigator becomes unable to continue Project, and a mutually acceptable substitute is not available, Institution and/or Sponsor shall have the option to terminate said project.</p>
<p>1.4 Period of Performance. The Agreement is effective as of the Effective Date and terminates as of the End Date.</p>	
<p>1.5 Costs and Payments. This Agreement is designated as either: [9], [10]</p> <p>Cost-Reimbursable. If this Agreement is designated as “Cost-Reimbursable,” Company will reimburse Institution for the Cost of conducting the Research Program. The parties estimate that the Cost is sufficient to support the Research Program, but Institution may submit to Company a revised budget requesting additional funds if costs are reasonably projected to exceed the Cost. Company is not liable for any payment in excess of the Cost except on Company’s written agreement. Institution has the authority to rebudget Costs from time to time, at the discretion of the Principal Investigator, as long as the rebudgeting is consistent with the goals of the Research Program. At the end of the Research Program, if the balance owed to Company is \$100 or less, Institution may keep the balance. [11]</p> <p>--or--</p>	<p>[9] Fixed-Price agreements are rare- usually for a one-off experiment.</p> <p>[10] ONLY EITHER A or B will be in the agreement.</p> <p>[11] “Costs” will generally include direct and indirect costs. Many institutions charge an indirect cost rate that is around 50% of the direct costs (salaries and supplies). Overhead for research done off campus is often only about 30%. Research is usually done on-campus because the needed facilities are there.</p> <p>Many institution research agreements do not include performance bonuses, milestone payments, or the like. Private institutions may want to include such terms.</p> <p>The Company may want to include language for the cost-reimbursement option to include an obligation that the Institution include an accounting of costs along with any invoices. Also note that normally Sponsored Research Agreements will include payment mechanics such as when and how payments will be made.</p>

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<p>Fixed-Price. If this Agreement is designated as “Fixed Price,” Company will pay Institution the Cost indicated on page 1. The parties estimate that the Cost is sufficient to support the Research Program. Institution may submit to Company a revised budget requesting additional funds if Company requests a change in the Research Program scope of work. Company will not be liable for any payment in excess of the Cost except on Company’s written agreement. Institution has the authority to rebudget costs at the discretion of the Principal Investigator, as long as the rebudgeting is consistent with the goals of the Research Program. Company is not entitled to any refund of unspent funds if all Research Program commitments have been met. Institution will provide its customary final financial report upon Company’s written request.</p> <p>[12]</p>	<p>[12] Possible alternative 1.5:</p> <p>Sponsor will pay the Institution an amount equal to its reasonable, documented expenditures and reasonable overhead (such overhead to not exceed the rate set forth in Institution’s indirect rate agreement with the U.S. Federal Government) in conducting the Research Program subject to a maximum expenditure limitation of \$XXX, provided that in any and all events, the amounts charged by Institution shall not, without Sponsor’s prior written consent, exceed the amount. Payments shall be made as follows (subject to the possible later return of funds if uncommitted and unexpended, under Section 3.3):</p> <p>(a) Upon execution of all parties to the Agreement: \$ XXXX;</p> <p>(b) \$XXX by XXXX ; and</p> <p>(c) \$XXX by [date]</p> <p>Payments should be made within 30 days of the receipt of an undisputed invoice sent via mail and email and payable to The Institution. They should reference to the Principal Investigator, Agreement number and title of the Research Program funded under this Agreement and be submitted to the address set forth here.</p>
<p>2. INTELLECTUAL PROPERTY</p>	
<p>2.1 Definition of Technology. “Technology” means all tangible materials, inventions, works of authorship [13], software, information, and data conceived or developed in the performance of the Research Program.</p>	<p>[13] Works of authorship are included to cover copyrightable material.</p>
<p>2.2 Ownership of Technology. Institution owns the entire [14] right, title, and interest, including all patents, copyrights, and other intellectual property rights, in and to all Technology developed using Institution facilities and by Institution personnel under this Agreement (“Institution Technology”). Company owns the entire right, title and interest, including all patents, copyrights, and other intellectual property rights, in and to all Technology developed using Company facilities and by Company personnel under this Agreement (“Company Technology”). Technology that is jointly [15] developed by Institution and Company personnel will be jointly owned (“Joint Technology”).</p> <p>[16]</p>	<p>[14] Company should be aware of Bayh Dole licensing provisions that can attach to inventions arriving under an SRA. The Bayh Dole Act (35 U.S.C. §200-212) allows universities to retain ownership of their inventions developed through use of federal funds but grants the Government a royalty-free nonexclusive license to the invention. Thus, it is important to identify the source of any funds used in making an invention under the SRA. Government rights attach to an invention even if only \$1 of federal funding is used in conceiving, or first actually reducing to practice, the invention.</p> <p>[15] This are often no provisions addressing joint ownership of inventions beyond what is found in</p>

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	<p>§2.2 and §2.6. It may be desired to elaborate on “Joint Technology,” if important joint inventions are expected to arise. Parties often avoid elaborating on how joint ownership will be handled, because it complicates the agreement. One solution is to establish a lead owner of the joint technology who is responsible for protecting and administering the joint invention. Terms for cost sharing and income distribution can be included.</p> <p>[16] Possible addition:</p> <p>Inventorship shall be determined by the patent laws of the United States and initial ownership shall follow inventorship. Each Party shall retain all of its right, title and interest in and to any and all inventions made prior to, or outside the activities of, this Agreement. Except as expressly set forth herein, no license, express or implied, is granted with respect to any patents, patent applications, know-how (whether patentable or unpatentable) or other intellectual property rights of the other Party.</p> <p>Possible addition:</p> <p>Institution hereby grants to Sponsor a perpetual, irrevocable, worldwide, non-exclusive, royalty free right and license, with the right to sublicense to third parties through multiple tiers, to use the Data and Results for any and all purposes. Data and Results mean all data, information and results arising from the Research Program that are included in the Research Program deliverables but are not inventions and discoveries for which a patent invention disclosure is made.</p> <p>Another alternative clause, depending on the type of research, provides that the Company may negotiate a clause whereby the Data and Results are solely owned by the Sponsor. The rationale is that the Sponsor paid for these results.</p>
<p>2.3 Patent Filing and Expenses. Institution may file patent applications covering Institution Technology (“Institution Patents”) at its own discretion and expense, or at the request of Company at Company’s expense. If Company elects to license Institution Patents, Company will pay the costs of patent filing, prosecution and</p>	<p>[17] This section is directed to patent costs incurred during the term of the research project and prior to licensing of said patent. Patent costs will also be addressed in any subsequent option or license arising from the SRA.</p> <p>[18] Possible additions:</p>

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maintenance in the United States and any foreign country elected [17]. Institution Patents include any foreign patent application corresponding thereto, and any divisional, continuation, or reexamination application, extension, and each patent that issues or reissues from any of these patent applications. Institution Patents do not include any continuation-in-part (CIP) patent application or patent. Company will notify Institution of those countries outside the United States in which it desires a license in sufficient time for Institution to satisfy the patent-law requirements of those countries. Company will reimburse Institution for out-of-pocket costs for those filings, including patent filing, prosecution, and maintenance fees. [18]

Background Intellectual Property. Both parties agree to identify in advance, and/or during the course of the Agreement, background intellectual property that has value for practicing Institution Technology or Company Technology as defined §2.2, but was developed with separate funds outside of this Agreement. Background Intellectual Property does not qualify as Institution Technology or Company Technology and is not subject to terms relating to technology conceived or reduced to practice under this Agreement.

Possible addition:

Institution discloses and grants an exclusive royalty-free license to any of its Background Intellectual Property that is necessary to practice any anticipated inventions resulting from the program. The Sponsor will use this Background IP only to the extent necessary to practice any inventions resulting from the program.

Often, Institution will want to control patent filings. Company will pay patent costs and will have the right to license the patent(s). However, if Sponsor elects to license and pay prosecution and maintenance expenses, then Sponsor likely will want some control over prosecution decisions or at least the ability to provide input. If Sponsor elects to a non-exclusive license, Sponsor can argue that it should not have to pay all of the prosecution and maintenance expenses. Details of patent prosecution and expenses are often handled in a separate license agreement. It is also possible to negotiate to have parties split cost of patent prosecution and maintenance.

Sponsor may also want to include language in this section providing that the Company has the right to review, comment, and possible even approve any patent prosecution prior to submission to a patent office.

Possible addition:

Claims in a CIP that are supported by an Institution Patent will be treated as Institution Patents and subject to this agreement.

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<p>2.4 Invention Disclosure and License Election. Institution will provide Company with a complete, written, confidential disclosure of Institution Technology after the disclosure is received by Institution’s Office of Technology Licensing. By giving written notice to Institution within three months after receipt of the disclosure, Company may elect one of the following alternatives: [19]</p> <p>Non Exclusive License. Subject to third-party rights, if any, a nonexclusive, nontransferable (without the right to sublicense), worldwide license in a designated field of use to make, have made, use, and sell products covered by the Institution Patents on terms to be negotiated. A non-exclusive license granted under this section may provide that , Institution may at its option discontinue patent prosecution or maintenance of any such invention licensed to Company for which Institution is paying patent-related costs; or</p> <p>Exclusive License. Subject to third party rights, if any, a royalty-bearing, limited-term, exclusive, field-of-use license, including the right to sublicense, in the United States or any other country elected by Company (subject to Section 2.3 above) to make, have made, use, and sell products covered by the Institution Patents, in exchange for Company’s agreement to diligently commercialize the invention. [20]</p> <p>[21], [22]</p>	<p>[19] A license can’t be both exclusive and non-exclusive. For each invention, the Company may choose either a non-exclusive agreement or an exclusive agreement.</p> <p>[20] <i>Alternative for exclusive:</i></p> <p>Institution hereby grants Company an option to a royalty-bearing, sublicensable, exclusive license in Institution Inventions and Institution’s interest in Joint Inventions for such territories as Company may request. Company may exercise its option to such exclusive license at any time within six (6) months after Institution notifies Company of a new Invention. ("Option Period"). In the event Company notifies Institution in writing that it wishes to exercise its option to an exclusive license during the Option Period, the Parties shall have six (6) months ("Negotiation Period") to agree on the terms of such license, which shall be negotiated in good faith under commercially reasonable terms. In the event that (a) Company fails to notify Institution of its desire to exercise its option to an exclusive license during the Option Period, or (b) Company notifies Institution that it does not wish to exercise its option to an exclusive license, or (c) the Parties are unable to agree on the terms of such license by the end of the Negotiation Period, then Institution shall have no further obligation to Company with respect to such Invention except that Company’s internal research use license shall continue in effect.</p> <p>[21] Parties often include a dispute resolution provision for situations in which they cannot agree on terms. See §11.1.</p> <p>[22] Possible Alternative:</p> <p>Include an exhibit with licensing terms outlined. See Exhibit B. Institution hereby grants Company an option to obtain an exclusive option to Institutions Patents as defined herein in accordance with the provisions of Exhibit B, which is incorporated into and made a part of this Agreement.</p>
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<p>2.5 License Terms and Conditions. All licenses of this Section 2 elected by Company are effective as of the date the parties negotiate and sign a separate license agreement, which will contain indemnity[23], insurance, and no-warranty provisions, in addition to other customary terms and conditions. Company agrees all licenses will be subject to applicable laws and regulations. [24]</p> <p>[25]</p>	<p>[23] Many public institutions are required by state law to include terms for indemnity of the institution. Alternative language may exclude indemnity for Institution’s gross negligence or willful misconduct. Institution may agree to indemnify company for damages caused by negligent or intentional acts or omissions of Institution.</p> <p>[24] The term “applicable laws” as found in this university example is vague. It probably refers to jurisdictions where licenses must be filed with the government.</p> <p>[25] Possible addition:</p> <p>In the event that the parties are unable to agree on licensing terms under this §2, the dispute resolution set forth in §11.1 may be invoked by either the Institution or the Company.</p>
<p>2.6 License to Joint Technology. Company may, at its option under Section 2.4, exclusively license Institution’s rights in Joint Technology.</p>	
<p>2.7 Copyright Licenses. Company may elect to negotiate a nonexclusive or exclusive (subject to third party rights, if any) royalty-bearing license to use, reproduce, display, distribute and perform computer software developed in the course of the Research Program (Institution Software) and its documentation for commercial purposes in a designated field of use. Company must elect within three months of notice of Institution’s disclosure of copyrightable material available for license. Computer software for which a patent application is filed is subject to Sections 2.3 and 2.4.</p> <p>[26], [27]</p>	<p>[26] Possible addition:</p> <p>Company may further elect to negotiate a nonexclusive or exclusive to existing data and know how used in Institution Software.</p> <p>[27] This Section may also be modified to refer to §11.1 and/or may be modified to extend the three-month period.</p>

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<p>2.8 Negotiation Period and Non-Election. If Company does not provide written notice of election to Institution within three months [28] of a written disclosure under Section 2.4, Institution has no further license obligations to Company. If Institution and Company fail to complete license negotiations within three months after written election, Institution has no further license obligations to Company.</p>	<p>[28] The Company may want to lengthen these time periods or specify negotiation procedures. “Good faith negotiations” may be specified. It may also want to include language to the effect that if parties fail to negotiate final terms, they are subject to §11.1’s dispute resolution provision.</p>
<p>2.9 Assignment. [29] Institution represents that all of its employees, students, and consultants who participate in the Research Program will be obligated to assign to Institution all their rights in patentable or copyrightable Technology.</p> <p>2.10 Expendables and other equipment. Institution owns all expendables and equipment purchased or fabricated to perform the Research Program.</p> <p>2.11 Other Intellectual Property. For the avoidance of doubt, all intellectual property developed outside of this Agreement shall remain the property of its owner. Except as explicitly provided in this Agreement, neither party receives any right to the other’s intellectual property developed outside of this Agreement.</p>	<p>[29] Students may not be required to sign the institution’s patent agreement. Be sure that students working under the SRA have signed the Institutions patent agreement. This is important because the Institution may be is granting licenses to the Sponsor.</p>
<p>3. REPORTS</p>	
<p>3.1 Reports. The parties will generally keep one another informed of the results of the work performed in connection with the Research Program. [30], [31]</p>	<p>[30] Possible additions:</p> <p>Institution will usually furnish periodic reports and a final report. Company may use any unpatented reported technology. Institution will keep accurate financial and scientific records relating to the Research Program and will make such records available to Sponsor or its authorized representative throughout the Term of the Agreement, during normal business, hours upon reasonable notice.</p>
	<p>Sponsor’s representatives may consult informally with Institution’s representatives regarding the project, both personally and by telephone. Access</p>

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	<p>to work carried on in Institution laboratories in the course of these investigations shall be entirely under the control of Institution personnel but shall be made available on a reasonable basis.</p> <p>[31] Company may want to add more specifics regarding interim reports, final report.</p>
4. PUBLICATION	
<p>4.1 Objective. The basic objective of research activities at Institution is the generation of new knowledge and its expeditious dissemination for the public’s benefit. [32] Company will provide all reasonable cooperation with Institution in meeting this objective.</p>	<p>[32] Institution will not agree to keep any research findings as a trade secret. See 4.3. Institution may agree to keep Sponsor’s Confidential Info confidential. See possible addition to §4.2.</p>
<p>4.2 Confidential Information. [33] “Confidential Information” means Company-owned, confidential, scientific, business or financial information that is provided in written form and clearly marked as Confidential, provided that such information:</p>	<p>[33] This is a fairly standard definition of confidential information in academia. Note that it, in this form, there is no undertaking on its institution to guard the confidential information. See addition below. It is very common for an Institution to maintain Company’s identified confidential information in confidence and remove it from proposed publications at the request of the Company.</p>
<p>(A) is not publicly known or available from other sources who are not under a confidentiality obligation to the source of the information;</p>	
<p>(B) [34] has not been made available by its owners to others without a confidentiality obligation;</p>	<p>[34] Possible amendment: “has not routinely been...or has not been deliberately been...”</p>
<p>(C) is not already known by or available to Institution without a confidentiality obligation;</p>	
<p>(D) is not independently developed by the Institution; or</p>	
<p>(E) does not relate to potential hazards or cautionary warnings associated with the performance of the Research Program, or is not required to be disclosed under operation of law.</p>	
<p>[35]</p>	<p>[35] Possible additions:</p> <p>Sponsor may wish to disclose certain of its confidential and/or proprietary information (“Confidential Information”) to Institution during the term of this Agreement. Confidential Information will be transmitted in writing and clearly marked “Confidential,” “Proprietary,” or similarly, or if disclosed orally will be reduced to writing by Disclosing Party, clearly marked</p>

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	<p>“Confidential,” “Proprietary,” or similarly, and transmitted to the Contact Person of Receiving Party within thirty (30) days after oral disclosure. No license under or title to any invention, patent, trademark, trade name or other intellectual property or other rights or interests in the Confidential Information now or hereafter owned by or controlled by any Party is granted either expressly, by implication, estoppel or otherwise by the Agreement. All Confidential Information is provided “AS IS” and without warranty, express or implied, of any kind.</p> <p>Institution will use Confidential Information solely for the purpose of conducting the Research Program, and shall use reasonable efforts to prevent the disclosure of Confidential Information to third parties during the term of this Agreement and for a period of five (5) years after its expiration or termination.</p>
<p>4.3 [36] Review As a matter of basic academic policy, Institution retains the right at its discretion to publish freely the results of the Research Program. Institution will provide Company with a copy of any manuscript or other publication at the time it is submitted for publication. Company may review [37], [38]the manuscript or publication:</p>	<p>[36] Possible addition:</p> <p>Company understands that Institution may be involved in similar research on behalf of itself and others. Institution shall be free to continue such research provided that it is conducted separately from the Research Program hereinafter defined, and Sponsor shall not gain any rights via this Agreement to such other research. (favors institution)</p> <p>[37] Company may include language that ensures that it gets any manuscript or other public disclosure (e.g. poster paper) well in advance of disclosure.</p> <p>[38] Company may negotiate more than the right to “review” a manuscript for patent purposes. The Institution’s ability to “freely publish” can be modified to include some sort of right of approval before any publications.</p>
<p>(A) To ascertain whether Company’s Confidential Information would be disclosed by the publication;</p>	<p>[39] Possible addition to (A):</p> <p>..and require deletion of Company proprietary information.</p>

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<p>(B) To identify potentially patentable Technology so that appropriate steps may be taken to protect the Technology; and</p>	
<p>(C) To confirm that the privacy rights of individuals are adequately protected.</p>	
<p>4.4 Comments. Company will provide comments, if any, within 30 days [40] of receiving the manuscript or publication. If Company determines that the proposed publication contains patentable subject matter that requires protection, Institution agrees to the delay of the publication for a period of time not to exceed sixty (60) days for the purpose of allowing the pursuit of such protection.</p>	<p>[40] Early publication is important to academics and early filing is important for patent priority. Note that receiving the publication means that patent rights have been lost at this point. §4.4 should refer to a “proposed publication” and provide that Institution supply the manuscript or proposed publication at least a certain time before any public disclosure of results of the Research Program.</p>
<p>4.5 Acknowledgment. Institution will give Company the option of receiving an acknowledgement in resulting publications.</p>	
<p>5. EARLY TERMINATION</p>	
<p>5.1 Termination by Either Party. Either party may terminate this Agreement upon 60 days’ written notice[41]. [42]</p>	<p>[41] Institution may require Company to pay wind up costs for early termination. This is particular important where stipends or salaries depend on the research support.</p> <p>[42] Possible addition/alternative:</p> <p>A. Should Institution materially breach this Agreement or become unable to perform hereunder, Sponsor shall have the right to terminate this Agreement. Sponsor shall notify Institution in writing of its intention to terminate, and termination shall become effective thirty (30) days thereafter if, during such thirty (30) day period, Institution is unable to cure the breach or rectify its performance.</p> <p>B. Material breach of this Agreement by Sponsor and failure of Sponsor to pay any undisputed amount owed hereunder within thirty (30) days after receipt of an invoice from Institution shall be cause for Institution to terminate</p>

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<p>6. NOTICE</p>	
<p>6.2 Either party will provide written notice to the other party of a change in its address.</p>	
<p>7. PUBLICITY</p>	
<p>Neither party will use the name or trademark of the other party in any publicity, advertising or announcement related to this Agreement without the prior written consent of the other party. [43]</p>	<p>[43] Institution will require right to review any press releases using its name. Institutions are very concerned about possible misuse of their names. This is distinct from publication rights.</p>
<p>8. INDEMNITY</p>	
<p>Company will indemnify [44], defend, and hold harmless Institution its trustees, directors, employees, agents, volunteers, subcontractors, and students (“Indemnitees”) from any liability, damage, loss, or expense (including reasonable attorneys’ fees and expenses of litigation) incurred by or imposed upon the Indemnitees or any one of them in connection with claims, suits, actions, demands, or judgments arising out of or connected with: (a) Company-provided materials or equipment used in the Research Program, (b) human subjects involved in the Research Program, and (c) Company’s use of results of the Research Program, except to the extent that the liability is due to the gross negligence or willful misconduct of Institution. Institution will promptly notify Company of any claim and will cooperate in the defense of the claim. Company will, at its own expense, provide attorneys reasonably acceptable to Institution to defend against any claim for which Company has agreed to indemnify Institution. This indemnity will not be deemed excess coverage to any insurance or self-insurance Institution may have covering a claim. Company’s indemnity will not be limited by the amount of Company’s insurance.</p>	<p>[44] Company may ask for reciprocal indemnification from the Institution. Institutions rarely agree to indemnification of a Company, but a Company may negotiate carve-outs for indemnification of damages caused by Institution’s gross negligence, etc. as set forth in §8(c).</p>
<p>8.4 A party’s indemnity shall not be limited by the amount of the indemnifying party’s insurance. [45]</p>	<p>[45] Institution may require Company to have product liability insurance. Institution may be required to have worker’s compensation insurance. This section may also be a set limit for the financial limit on the indemnifying party. The Company may also be required to provide a certificate of insurance to cover activities under the research agreement.</p>
<p>9. WARRANTIES AND LIABILITY LIMITS</p>	

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<p>9.1 No Guarantee. Company acknowledges that the Research Program is a scientific undertaking and, consequently, Institution will not guarantee any particular outcome or specific yield.</p>	
<p>9.2 Disclaimer of Warranties. Institution provides Company the rights granted in this Agreement AS IS and WITH ALL FAULTS. Institution makes no representations and extends no warranties of any kind, either express or implied. Among other things, Institution disclaims any express or implied warranty:</p>	
<p>(A) of merchantability, of fitness for a particular purpose,</p>	
<p>(B) of non-infringement or</p>	
<p>(C) arising out of any course of dealing.</p>	
<p>9.3 No Damages. NEITHER PARTY SHALL BE LIABLE FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL, OR INCIDENTAL DAMAGES SUFFERED BY THE OTHER PARTY, ANY LICENSEE, OR ANY OTHERS INCLUDING, BUT NOT LIMITED TO, DAMAGES ARISING FROM LOSS OF DATA OR DELAY OR TERMINATION OF THE RESEARCH PROGRAM, OR FROM THE USE OF THE RESULTS OF THE RESEARCH PROGRAM, THE USE OF ANY RESEARCH MATERIALS OR ANY SUCH TECHNOLOGY OR PRODUCT. EACH PARTY ACKNOWLEDGES AND AGREES THAT THIS EXCLUSION AND LIMITATION IS REASONABLE CONSIDERING THE EXPERIMENTAL NATURE OF THE RESEARCH PROGRAM AND THE NATURE AND TERMS OF THE PARTIES' RELATIONSHIP.</p>	
<p>10. COMPLIANCE</p>	
<p>10.1 Laws and Regulations. Each party is subject to all local, state and federal laws and regulations applicable to its obligations under this Agreement.</p>	
<p>10.2 Export Control. [46] Both parties agree to adhere to U.S. export laws and regulations, where applicable. Company agrees</p>	<p>[46] Important for possible military applications, including satellites. Usually this a is a mutual undertaking as the sponsor is not responsible for</p>

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<p>that it will not disclose Confidential Information that contains technology or technical data identified on any U.S. export control list, including the Commerce Control List (“CCL”) at 15 C.F.R. 774 and the U.S. Munitions List (“USML”) at 22 C.F.R. 121. Proposed disclosures of Confidential Information by Company that include technology or technical data other than that classified as EAR99 will be negotiated pursuant to a separate agreement.</p>	<p>the Institution sharing export-controlled technology unlawfully with its students, professors, staff or consultants.</p>
<p>10.3 Animal Studies. Institution does not conduct animal studies that are intended to support applications for research or marketing permits for FDA-regulated products (as described in Title 21, Code of Federal Regulations (CFR) Part 58-Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies).</p>	
<p>10.4 Human Research Protection Program. [47]Company acknowledges that Institution has a human research protection program (“HRPP”) established in accordance with the principles and standards of the Association for the Accreditation of Human Research Protection Programs that is applicable to all research involving human subjects, including the Research Program, that includes: (i) submittal for prospective and continuing review to Institution’s institutional review board (“IRB”) under the federal regulations governing the protection of human research subjects, (ii) obtaining consent from human research subjects as specified in those regulations, (iii) conducting the research in accordance with ethical standards such as the Belmont Report.</p>	<p>[47] Some institutions do conduct FDA related clinical trials. A separate type of agreement is used for these. Section 10.4 contemplates the use of human subjects for other than FDA related purposes.</p>
<p>(A) Communication Concerning Certain Events Affecting Research Participants. In furtherance of Institution’s HRPP, Company agrees:</p>	
<p>(1) to notify promptly the Principal Investigator and/ or the Institution IRB directly, of (i) non-compliance with the Research Program in Exhibit A or applicable laws, particularly those laws related to human research subjects, that could affect the safety or welfare of participating subjects; (ii) serious adverse events that have been reported to the FDA or other governmental agency in relation to the Research Program at Institution or any other site; (iii) unanticipated problems in the Research Program at Institution or any other site that could relate to risks to</p>	

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<p>participating subjects; and (iv) circumstances that could affect subjects’ willingness to continue to participate in the Research Program or the continued approval of Institution’s IRB for the Research Program, and</p>	
<p>(2) to develop a plan of communication to subjects with Institution’s Principal Investigator that is acceptable to Institution’s IRB when new findings or results of the Research Program might affect the willingness of subjects to continue to participate in the Research Program or directly affect their current or future safety or medical care.</p>	
<p>(B) Data and Safety Monitoring Reports. Company will provide Institution with any data and safety monitoring reports related to the Research Program that may: (i) affect the safety and welfare of current or former Research Program participants, or (ii) influence the conduct of the Research Program. Institution will submit such reports to the IRB as required. During the Research Program and for at least two (2) years following the completion of the Research Program at all sites, Company will promptly provide Institution and Principal Investigator with the written report of any routine monitoring findings in site monitoring reports and data safety monitoring committee reports including, but not limited to, data and safety analyses that may: (i) affect the safety and welfare of current or former Research Program participants, or (ii) influence the conduct of the Research Program.</p>	
<p>11. GENERAL PROVISIONS</p>	
<p>11.1 Dispute Resolution. If any dispute [48] arises between the parties under this Agreement that cannot be resolved by mutual agreement after meetings between the parties, it will be finally settled under the JAMS Comprehensive Arbitration Rules and Procedures, by one or more arbitrators appointed in accordance with the Rules. Arbitration will be held in [city], California, or at some other mutually agreeable location.</p>	<p>[48] Possible Addition: This provision also applies to the licensing negotiations, if appropriate, in Section 2. Sample clause: “If any dispute arises, including a dispute concerning terms of a licensing agreement negotiated under this Agreement...”</p>
<p>11.2 Assignment. Neither party may assign this Agreement without the prior written notice to the other party.</p>	
<p>11.3 Severability. If any provision of this Agreement becomes or is declared illegal, invalid, or unenforceable, the provision will be divisible</p>	

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<p>from this Agreement and deemed to be deleted from this Agreement. If the deletion substantially alters the basis of this Agreement, the parties will negotiate in good faith to amend the provisions of this Agreement to give effect to the original intent of the parties.</p>	
<p>11.4 Independent Contractors. Institution and Company are independent contractors and neither is an agent, joint venturer, or partner of the other.</p>	
<p>11.5 Governing Law. This Agreement is governed by the laws of the <u>State of California</u> [49], without regard to its conflict of laws doctrine. Any legal action involving this Agreement or the Research Program will be adjudicated in the State of California.</p>	<p>[49] If the Institution is in California.</p>
<p>11.6 Non-Discrimination. [50] Institution shall follow its normal employment policies, which prohibit discrimination against any employee or applicant for employment on the basis of race, color, creed, religion, national origin, sexual preference, marital status, age, sex, or handicap (except where bona fide occupational qualification so requires), with respect to this Agreement. Qualified individuals will not be denied the opportunity to contribute to the work to be conducted at Institution under this Agreement on the basis of citizenship.</p>	<p>[50] Typical Institution policy but is often optional in the Agreement.</p>
<p>11.7 Force Majeure. [51] Institution is not liable for any failure to perform as required by this Agreement if the failure to perform is caused by circumstances reasonably beyond Institution’s control, such as labor disturbances or labor disputes of any kind, accidents, failure of any governmental approval required for full performance, civil disorders or commotions, acts of aggression, acts of God, energy or other conservation measures, explosions, failure of utilities, mechanical breakdowns, material shortages, disease, theft, pandemic, or other occurrence.</p>	<p>[51] Company may ask for reciprocal force majeure clause.</p>
<p>11.8 Prevailing Terms. In the event of any inconsistency between the terms of this Agreement and the documents referenced or incorporated into this Agreement, the terms of this Agreement prevail.</p>	

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<p>11.9 Entire Agreement. This Agreement represents the entire agreement and understanding between the parties with respect to its subject matter. It supersedes all prior or contemporaneous discussions, representations, or agreements, whether written or oral, of the parties regarding this subject matter.</p>	
<p>11.10 Amendments or Changes. Amendments or changes to this Agreement must be in writing and signed by the parties' authorized representatives.</p>	
<p>11.11 Electronic Signatures. The parties to this Agreement agree that a copy of the original signature (including an electronic copy) may be used for any and all purposes for which the original signature may have been used. The parties further waive any right to challenge the admissibility or authenticity of this Agreement in a court of law based solely on the absence of an original signature.</p>	
<p>11.12 Counterparts. This Agreement and any amendment to it may be executed in counterparts and all of these counterparts together shall be deemed to constitute one and the same agreement.</p>	
<p>The duly authorized party representatives execute this Agreement, including all its terms and conditions.</p>	
<p>INSTITUTION</p> <p>Signature: Name: Title: Date:</p>	
<p>COMPANY</p> <p>Signature: Name: Title: Date:</p>	

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<p>[52] I acknowledge that I have read this Agreement in its entirety and will use reasonable efforts to uphold my obligations and responsibilities under this Agreement.</p> <p>PRINCIPAL INVESTIGATOR</p> <p>Signature: Name: Title: Date:</p>	<p>[52] The PI will sign here- his or her participation is critical. The PI will ordinarily be a faculty member authorized to sign on behalf of the institution. Depending on the Institution, the PI may or may not sign the SRA.</p>
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EXHIBIT A

RESEARCH PROGRAM: Study of HFF as a potential therapy for AKH

Background

Sponsor is interested in pursuing a preclinical study on aggravation Kontract hair loss (AKH), a rare genetic bone disease characterized by the formation of bone maladies. Sponsor is developing human hair factor (HFF) as a potential therapy for AKH. Dr. X at Institution has expertise and an appropriate mouse model for AKH testing.

Objective

Principal Investigator will use his expertise and AKH mouse model to test Sponsor's drug, HFF, to generate preliminary data on the potential therapeutic effect of HFF.

Aims

1) Breeding of test animals: The first phase of the project is breeding to produce sufficient numbers of test animals (certain genetic backgrounds). Two groups of mutant mice will be administered with two different doses of HFF, one group of mutant mice will be administered with vehicle only, and one group of phenotypically normal littermates will be untreated. The number of mice per group will be 10, which is sufficient to have enough statistical power. To produce these numbers of test animals, multiple rounds of breeding are necessary, which encompasses more than 2,000 cage-days and 50 weeks. Genotyping of animals will be performed by PCR.

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- 2) Administration of HFF for experimentation. Once a sufficient number of test animals have been produced in Aim 1, above, drug administration experiments will be performed on these mice. HFF will be administered by oral gavage daily for 6 weeks, starting on day 15.
- 3) Evaluation of osteochondroma formation. At the end of drug treatment in Aim 2, above, all of the mice will be sacrificed to prepare alcian blue/alizarin red-stained whole-mount skeletal preparations. In these skeletal preparations, the formation of osteochondromas will be assessed in long bones in limbs, rib bones, and vertebrae.

Training Component

The studies described above will include a training component wherein postdoctoral trainees will perform some of the experiments. This will provide postdoctoral trainees in-depth opportunities to learn about the underlying science and technology, and the design and interpretation of research results. The Principal Investigator will provide mentoring for all aspects of the postdoctoral trainees' work under the Research Program, which could involve, among other things, providing training in research design and methods, data interpretation, verbal and written communication and career advice.

Estimated Project Duration: within 12 to 18 months

Total Estimated Budget: [\$] USD.

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EXHIBIT B

SUMMARY OF TERMS FOR PROPOSED PATENT LICENSE AGREEMENT

TECHNOLOGY TITLE: HFF as a potential therapy for AKH

INVENTORS: XXX

This document is intended to describe, for negotiation purposes only, certain principal terms of the INSTITUTION’s Patent License Agreement to Company.

Confidentiality

The terms and conditions of this Term Sheet shall be confidential information and shall not be disclosed to any third party without the consent of the Institution and the potential Licensee (Parties), except that the Parties may disclose the terms and conditions described in this Term Sheet including its existence to their respective officers, directors, employees, attorneys and other advisers, provided that such persons agree to the confidentiality restrictions contained herein.

Licensee (name and address)	Company
Licensor	The INSTITUTION
License Grant	Exclusive or Non-Exclusive
Licensed Patent(s)	As disclosed in Section 2.4
Licensed Field	The patent license will specify the field of use in which licensee may practice the licensed patent(s) and/or patent application(s). In some cases, a licensee is permitted to practice in all fields. In other cases, a licensee will be granted the right to practice only in a specific field which will be clearly defined in the Patent License. The breadth of the Field of Use depends upon the licensee’s ability to effectively commercialize the technology covered by the patent and/or patent applications, whether the license is non-exclusive or exclusive, and the novelty of the technology.
Territory	The Patent License will specify the territories in which a licensee may practice the patent(s) and/or patent application(s), and technology. In some cases, the territory will be worldwide. In other –less common--cases, the licensee’s rights will be limited to a country or list of countries.
Sublicensing	The Patent License will specify whether the Licensee will be permitted to sublicense its rights to other entities. All sublicenses must be subject to substantially similar terms and conditions of the Licensee’s agreement, such as insurance, confidential information, etc., and that the Licensee remains liable for sublicensee’s acts or omissions.
Future Patent Expenses	In exclusive licenses, licensee will pay all future patent expenses; sometimes a fraction if agreement is co-exclusive.
Patent Prosecution	INSTITUTION generally will control the prosecution of all licensed patents and/or patent applications and will own all licensed patents and/or patent applications. In certain instances, as agreed upon by the INSTITUTION, licensee may take the lead in patent prosecution if the INSTITUTION’s approved patent counsel agrees to designate both Licensee and INSTITUTION’s co-clients

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Insurance	As in Sponsored Research Agreement
Use of Name	As in Sponsored Research Agreement
Assignment	Licensee may not assign the license without the prior express written consent from the INSTITUTION. Assignment is usually permitted when company or business unit is sold.

Licensing Fees

The Patent License agreement will contain some combination of the following fees:

Upfront Fees	\$XX will be paid to the INSTITUTION upon execution of the license.
Past Patent Expenses	\$ XX will be paid to INSTITUTION upon execution of license by licensee. Probably covered by the Sponsored Research Agreement.
License Maintenance Fee	\$XX will be paid to INSTITUTION upon each anniversary of the license until such time as earned (running) royalties are paid.
Running Royalty	__X _% will be paid to INSTITUTION based on licensee revenue from net sales of licensed products or services within 30 days of the end of each calendar quarter.
Minimum Royalty	Minimum annual royalty payments: Year __1__ \$ _____; Year __2__ \$ _____; etc.
Sublicense Fees and Royalties	Licensee shall pay to the INSTITUTION __ % of any and all fees, cash consideration, or the fair market value of non-cash consideration received from sublicensees. In addition, Licensee shall pay to the INSTITUTION a royalty which rate shall be the greater of (a) __% of the royalty rate charged by Licensee on net sales by such sublicensee, or; (b) the same rate that would be due to the INSTITUTION from net sales by LICENSEE.
Equity	Licensee will issue __ number of shares of Licensee's Series __ Preferred Stock which represents a valuation of \$_____ and equals __% of the aggregate of all classes of Licensee's shares on a fully diluted basis as of _____, 200__ (e.g., the Effective Date, the date of the Series __ closing, etc.). Such issuance will be subject to acceptance by the INSTITUTION of the terms set forth in Licensee's Series __ Stock Purchase Agreement and related agreements governing shareholder rights which will contain terms and conditions common to all other Series __ investors. INSTITUTION will accept an equity interest in lieu of certain cash payments. The INSTITUTION will be treated in the same manner as other stockholders holding similar shares invested in the Licensee (e.g. All rights and privileges that apply to stockholders holding Series A preferred stock must apply to INSTITUTION.

Commercial Diligence

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Diligence Milestones	<p>Licensee must demonstrate technical and commercial diligence by meeting the following milestone schedule, in some cases a milestone payment will be included:</p> <p>Milestone 1: (research milestones) ___ years from the Effective Date: Licensee will _____;</p> <p>Milestone 2 (research milestones) : ___ years from the Effective Date:</p> <p>Licensee will pay INSTITUTION \$_____ dollars for __Milestone _____;</p> <p>Exemplary Milestones: proof-of-principal experiments; completion of prototype; obtaining a level of funding; granting of a sublicense, initiation of pre-clinical trials; clinical phases; filing NDA, etc.</p>
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