<u>UCLA Implementing Procedures on Policy Exceptions Under the 2024 UC Policy on</u> <u>Inventions, Patents, and Innovations Transfer</u>

In early 2024, President Drake issued the new UC Policy on Inventions, Patents, and Innovation Transfer ("UC Patent Policy"), which supersedes the 1997 Policy, and becomes effective on July 1, 2024.

Under the 2024 UC Patent Policy, each UC location may issue their own local standing exceptions. The 2024 Policy shifts authority for policy exceptions from UCOP to UC locations. To ease the transition to location-issued exceptions, UCLA has modified the Research Policy and Analysis Coordination Memos that were issued standing exceptions for the 1997 UC Patent Policy and developed these implementing procedures to fit the needs of UCLA.

The UCLA Chancellor has delegated UCLA DA XXX.XX to the UCLA Technology Development Group (TDG) to approve and implement the following exceptions:

- Non-Exclusive Royalty-Free Invention Rights (NERF)
- Academic Visitors' IP
- Non-Academic and Foreign Visitors' IP
- Patent Policy Guidelines for Agreements with Private Sponsors for Drug and Device Testing
- UC Policy on Inventions, Patents, and Innovation Transfer Exemptions

The UCLA Chancellor has delegated UCLA DA XXX.XX to the UCLA Clinical Trials Contracts & Strategic Relations (CTCSR) to approve and implement the following exceptions:

- Non-Exclusive Royalty-Free Invention Rights (NERF)
- Patent Policy Guidelines for Agreements with Private Sponsors for Drug and Device Testing

In accordance with their delegated authority and consistent with related UCLA and UC policies and guidance, TDG and CTCSR will implement the following procedures:

1. Non-Exclusive Royalty-Free Invention Rights (NERF)

The NERF provides UCLA (the "University) greater flexibility in negotiating rights to University inventions made in the performance of a sponsored research agreement across a wide range of industry research sponsorship.

Technology Development Group ("TDG") and/or Clinical Trials Contracts & Strategic Relations ("CTCSR") as applicable, have authority to grant a for-profit sponsor the first right to negotiate a royalty-free, non-exclusive (research or commercial) license to the University's interests in patentable inventions conceived and first reduced to practice in the performance of a research project. This NERF authority must be applied in a manner consistent with the University Policy and the guidelines described below:

a. PUBLIC BENEFIT – It is the responsibility of the University to ensure that future research results be diligently moved to the marketplace for the public good. The key

consideration here is whether the commitment of a NERF restricts the University's ability to ensure that the public interest is served.

- b. LEGAL INTEGRITY AND CONSISTENCY must enable the University to satisfy its agreements with third parties, including the Federal government and Tax regulations.
- c. INFORMED PARTICIPATION should inform the project manager (PI) of the potential lack of licensing income for any grant of rights to a royalty-free commercial license. The PI will be responsible to inform his research team members.
- d. FAIR CONSIDERATION –University has a responsibility to manage its assets for the public benefit and has an obligation to receive fair consideration in exchange for the grant of commercial licensing rights to a sponsor.

2. Academic Visitors' IP

To cultivate a more collegial approach regarding the ownership of intellectual property created by academic visitors, as well as simplify the patent policy administrative processes and requirements for processing academic visitors to the University, TDG is authorized to execute a pre-approved Visiting Academic Patent Agreement (Attachment A) in place of the standard University Patent Acknowledgement form for visitors that are:

- a faculty member or researcher from any accredited institution of higher education;
- a research scientist from a U.S. non-profit research institution; or
- a research scientist from a U.S. government agency.

The enclosed Academic Visitor Patent Agreement form (Attachment A) integrates the higher risk elements addressed by the University Patent Policy while respecting the cultural similarities shared among academic institutions. As such, the Academic Visitor Patent Agreement form embodies the following elements:

- a. Joint ownership of inventions and applicable works of authorship;
- b. Invention disclosure requirement to the University and visitor's employer;
- c. Visitor activity restrictions on: 1) Participating in University sponsored research projects; 2) Accepting/using University funds; 3) Using proprietary information or third-party proprietary research materials administered by the University with visitor activities performed at the University; and 4) Using University resources and facilities for private or third-party benefit;
- d. Third party conflict resolution provision; and
- **e.** Integration of the University t Policy requirements for inventions created outside the purpose of the visit.

3. Non-Academic and Foreign Visitors' IP

To foster a collaborative approach to the ownership of intellectual property created by non-academic and foreign visitors and to streamline the patent policy administrative processes and requirements for processing non-academic and foreign visitors to the University, TDG is authorized to implement a pre-approved Visiting Non-Academic Patent Agreement (Attachment B) instead of the standard University Patent Acknowledgement form for the

qualified visitors:

a. Qualified Visitor Criteria

- 1. The visitor's sole purpose is to engage in collaborative research, with no academic responsibilities, supervisory duties, or formal student advisory duties.
- 2. The visitor is not a UC student or a salaried UC employee.
- 3. The visitor and the visitor's employer do not appear on any of the U.S. government restricted party lists (e.g., the Department of Treasury Specially Designated Nationals List (SDN) or the Department of Commerce Entity List).
- 4. The visitor has a clear scope of work that describes the visitor's anticipated activities at the campus/Laboratory, including which facilities and/or equipment will be utilized. Detail should be sufficient to permit TDG determine, at a future time, whether an invention or discovery was created within or outside of the written scope of work.
- 5. The visitor does not use University gift, grant, or contract funds, except those possibly provided by the visitor's employer through a sponsored research agreement or collaboration agreement. Visitors associated with industry affiliates programs are not eligible under this standing exception.
- 6. The visitor's assignment of intellectual property to their employer does not conflict with the University's legal obligations with third parties, including the government or material providers.
- 7. The length of the researcher's visit is less than two years.
- 8. The visitor and an authorized representative of the visitor's employer signs the Visitor Patent Agreement without considerable modifications.

b. Implementation Criteria

- 1. University faculty member hosting the visitor agrees under an informed participation letter ("IPL") to work with campus/ administrators to ensure Visitor Criteria 1 through 7 above continue to be met throughout the duration of the visit.
- 2. The hosting faculty member's department dean, chairperson or director is willing to accept the financial and legal risks associated with accepting and complying with the Visitor Patent Acknowledgment and approves the visit as indicated by their signature.
- 3. University implements administrative processes to manage current and future extramural funding and material transfer to meet its intellectual property obligations to third parties and to avoid any conflict of obligations between the Visitor Patent Agreement and current or future sponsored research terms.
- 4. The visitor's use of University's resources financed with tax-exempt bonds do not fall under the safe harbor provisions of the Tax Reform Act of 1986. Such use must be monitored and constitutes private business activity regardless of how resulting inventions are handled. When combined with all other private business uses at the campus, such use must not exceed the private business use limits established by the IRS.
- 5. University follows applicable campus visitor procedures (that may not be related to intellectual property), including for example, those related to visa processing and

- Conflict of Interest.
- 6. University Export Control Officer reviews the scope of the visit and restricted party screening results for all foreign national visitors.
- 7. University exit review process is in place to ensure that the visitor does not take materials or University resources without prior approval and discloses all inventions at the end of their appointment.
- 8. University provides a copy of all executed Visitor Patent Agreements along with completed visitor intake forms and IPL's to Research Policy Analysis & Coordination at VisitorsExceptions@ucop.edu within 30 days of execution.

4. <u>UC Policy Guidelines for Agreements with Private Sponsors for Drug and Device Testing</u>

University medical schools and other health-related research facilities, with their faculty's hospital and clinic affiliations and access to patient populations, commonly conduct testing of new pharmaceutical and medical device products involving human patients.

TDG and/or CTCSR as applicable, have authority to confer greater patent rights to sponsors of drug and device studies, ranging from a free license to ownership of a narrow scope of specified inventions, if the research meets certain criteria:

- 1. The investigation to be undertaken is an FDA Phase I, II, III, or IV drug study or an FDA Regulated Medical Device Study. Preclinical studies are specifically excluded.
- 2. A private sponsor provides its proprietary product and study protocol to the University for the investigation.
- 3. The cost of the investigation conducted according to the Sponsor's protocol is fully funded by the Sponsor and is not supported in whole or in part with other funds, including Federal funds.
- 4. There are no known third-party rights to intellectual property of The Regents that would be compromised by granting rights to the clinical trial sponsor.
- 5. All administrative requirements have been satisfied:
 - 1. Informed Consent: Ensuring that all human subjects provide informed consent, which must be documented and maintained according to specific guidelines. This includes signing a consent form that is compliant with both federal and state laws.
 - 2. Compliance with Laws and Regulations: The agreements must comply with all applicable federal, state, and institutional regulations concerning human subjects research.
 - 3. Safety and Welfare of Participants: The agreements must ensure the safety and welfare of participants by adhering to rigorous safety protocols and monitoring for compliance throughout the study duration.
 - 4. Registration and Reporting: Clinical trials must be registered, and results must be reported as required under the Department of Health and Human Services

(DHHS) regulations and National Institutes of Health (NIH) policies. This includes updates to ClinicalTrials.gov as required by recent regulations, ensuring transparency and public accessibility of trial information.

5. UC Patent Policy Exemptions:

TDG has authorized the four categories of individuals that can be exempt from signing the University's Patent Agreement subject to the condition that the individual does not use University research facilities or contract, grant, or gift funds obtained through the University. The exempt categories are:

- a. U.S. government employees on assignment at UC but who are not compensated by UC;
- b. individuals on a short-term appointment (one year's duration or less) teaching a class or course that does not involve student research or design;
- c. clinical appointees who are not compensated by UC and not involved in UC clinical trials; and
- d. individuals using an approved recharge facility/equipment on behalf of an external party who is/are paying an approved external user fee.

In order to complete the exemption for individuals that fall into one of the four exemption categories noted above, Deans and Department Heads, as designated by this procedure, must approve the exemption and in conjunction with their HR manager ensure that the exemption is documented in the exempted individual's personnel file. A form like the one listed in Attachment C may be used for tracking and recording each approval.

Attachment A

ACADEMIC VISITOR PATENT AGREEMENT

constitutional corporation, hereinafter University campus and research facilit department, lab or school as appropri	called "University," in part consideries located at	
(Provide a brief description below of t	he purpose of the visit)	
Non-University Source of Funding/Ma	aterials (if any):	
University Faculty Host:	_Department/Unit:	

During the course of this Agreement, the parties agree that a primary reason for my presence at University is the fluid interaction between myself and the University research community, including faculty, researchers, and students. As such, it is the intention of the parties that the majority of the interactions involve the sharing of data that are not confidential to either party.

In exchange for the consideration listed above:

- 1. I will promptly report and fully disclose the conception and/or reduction to practice of potentially patentable inventions made by me, either solely or jointly with others, in the course of my activities at University ("Invention") to my Employer and the University's authorized campus/Laboratory licensing office.
- 2. I shall assign, and do hereby assign, jointly to my Employer and University all right, title and interest in any Invention and any applicable (under my employer's and University's intellectual property policies) works of authorship made by me in the performance of my activities at University, and to execute and deliver any transfers, assignments, documents or other instruments necessary or appropriate to effect such assignment.
- I acknowledge that any other inventions arising from my use of University resources and/or facilities are subject to University's Patent Policy (http://www.ucop.edu/ucophome/coordrev/policy/09-04-97patent.html).
- 4. I acknowledge that University's interest in my works of authorship created in the performance of my activities at University is limited to only such works as provided for in University's Policy on Copyright Ownership (http://www.ucop.edu/ott/staff/copyr.html).
- 5. I will not disclose to University or use in my activities at University any proprietary information or materials of my Employer or any third party, such information to include, without limitation, trade secrets or confidential information of such party.

- 6. I will not accept or use any gift, grant, or contract research funds through the University, participate in any sponsored research projects at University, perform any work for third party sponsors of research in University facilities, or perform any research at University using third party proprietary research materials administered by University without the prior written permission of University.
- 7. I will not use University funds, facilities or resources to conduct outside consulting activities.
- 8. Should my activities at University result in my participation in the conduct of research projects at University that are subject to third-party obligations, University and Employer will, to the extent possible, accommodate each other's obligations to such third-party sponsors of research.
- 9. If the parties cannot agree on an appropriate resolution under Item 8 above, the obligations to research sponsors shall take precedence. This Agreement shall be in effect from to . This Agreement may be terminated by either party upon giving of ninety (90) days advance written notice. This Agreement supersedes all previous agreements, oral or written, relating in whole or part to the performance of my activities as a visitor at University. I represent that I have not executed any agreements with or incurred any obligations to others in conflict with the foregoing, and will not, while bound by this Agreement, enter into any other agreements, or otherwise, that conflict with the foregoing. VISITOR UNIVERSITY (authorized campus licensing office director) Signature: Signature: Name: Name: Title: Title: Date: Date: ____ Acknowledged and accepted: VISITOR'S EMPLOYER UNIVERSITY HOST DEPARTMENT Name of Institution Department/Unit Name Authorized Representative (signature) Dean/Chairperson/Director (signature) Authorized Representative Name (print) Dean/Chairperson/Director Name (print)

Date

Date

Attachment B

NON-ACADEMIC VISITOR PATENT AGREEMENT

This Agreement is made by me with The Regents of the University of California, a corporation, hereinafter called "University," and with the understanding and agreement of my employer, <employer name=""> ("Employer"), in part consideration for my use of University campus and research facilities located at (insert campus, department, lab or school as appropriate) for the following purpose:</employer>		
Scope of Work: Provide a description below of the purpose of the visit:		
Non-University Sources of Funding/Materials:		
University Sources of Funding/Materials, if any:	-	
University Faculty Host:	Department:	

During the course of this Agreement, the parties agree that the primary reason for my presence at University is the fluid interaction between myself and the University research community, including faculty, researchers, and students.

- 1. I will promptly report and fully disclose the conception and/or reduction to practice of potentially patentable inventions made by me, either solely or jointly with others, in the course of my activities at University ("Invention") to my Employer and the University's authorized campus/Laboratory licensing office.
- 2. I shall assign, and hereby do assign, jointly to my Employer and University an equal and undivided interest to all right, title and interest in any Invention and any applicable (under my employer's and University's intellectual property policies) works of authorship made by me in the performance of my activities at University, and to execute and deliver any transfers, assignments, documents or other instruments necessary or appropriate to effect such assignment. To the extent that Employer is deemed to directly hold any rights to any Inventions by virtue of its employment of Researcher, Employer hereby assigns to University a joint interest in its rights, title and interest in Inventions.
- 3. I acknowledge that inventions created outside the Scope of Work involving my use of University funds, equipment, and/or facilities are subject to <u>University's Policy on Inventions, Patents, Innovations Transfers</u> unless agreed to otherwise in writing between the University and my Employer, and approved as an exception to Patent Policy by the Office of the President.
- 4. Except for information and materials explicitly listed under a sponsored research or collaboration agreement between my Employer and the University, I will not disclose to University or use in my activities at University any proprietary information or proprietary materials of my Employer

- or any third party, such information to include, without limitation, trade secrets or confidential information of such party.
- 5. Except for those provided by my Employer through a sponsored research or collaboration agreement, I will not accept or use any gift, grant, or contract research funds through the University, participate in any sponsored research projects at University, or perform any work for third party sponsors of research in University facilities without the prior written permission of University.
- 6. I will not use University funds, facilities or resources to conduct activities outside the Scope of Work.
- 7. Should my activities at University result in my participation in the conduct of research projects at the University that are subject to third-party obligations, Employer agrees that the University's legal obligations to third parties shall take precedence.
- 8. During my visit, I agree to abide by federal, state, and local laws and applicable University policies relating to safety and compliance.
- (OPTIONAL) Jointly owned patentable inventions created under this Agreement shall be managed by University and Employer in accordance with the attached Patent Management Agreement.

This Agreement is to be interpreted and construed in accordance with the laws of California.

This Agreement shall be in effect from ______ to _____, or until Visitor concludes his/her visit at University, whichever date occurs later in time. This Agreement may be terminated by either party upon giving of ninety (90) days advance written notice. Upon such termination, I will cease all use of University funds and facilities. The obligations to disclose and assign Inventions made by me in the performance of my activities at University in this Agreement will survive termination of this Agreement.

This Agreement supersedes all previous agreements, oral or written, relating in whole or part to my activities as a visitor at University. Furthermore, my Employer and I will not enter into any arrangements that conflict with my obligations under this Agreement.

I represent that I have not executed any agreements with or incurred any obligations to others in conflict with the foregoing, and will not, while bound by this Agreement, enter into any other agreements, or otherwise, that conflict with the foregoing.

VISITOR director)		<u>UNIVERSITY</u> (authorized campus licensing office	
Name:		Name:	
Title:		Title:	
Date:			
E mail:			

VISITOR'S EMPLOYER

 Organization Name:
 Signatory Name:
Signature:
 Title:
 Date:
 Phone:
E-mail:

Attachment C

Template Exemption Document

10: Employee's Personnel Record		
RE:		
(Name of Individual Being Exempted)		
Payroll Classification/Title:		
Employee ID Number:		
This is to certify that the above-named individual falls within the below marked category and will not use any University research facilities or contract, gift or grant funds obtained by or through the University in the course of their appointment.		
They therefore qualify for exemption from the University's requirement to sign the Patent/IP Acknowledgment.		
(Mark one of the following boxes)		
U.S. government employees on assignment at the University but who are not compensated by the University.		
Individuals on short-term appointment (one year's duration or less) teaching a class or course that does not involve student research or student design.		
Course Name and Number:		
Start Date: End Date:		
Clinical appointees who are not compensated by the University and not involved in University clinical trials.		
Individuals using an approved recharge facility/equipment on behalf of an external party who is/are paying an approved external user fee.		
External Party:		
(signed) Department Chairperson Date		
I,, agree that I will not use any University research facilities or gift, contract or grant funds obtained by or through the University in the course of my appointment. If I do, I understand that the Policy on Inventions, Patents, and Innovation Transfer will apply to my use of University Research Facilities or gift, contract or grant funds obtained by or through the University.		
(signed) Exempted Individual Date		