*Office of Research*
*and Funded Projects*

# Handbook

California State University,
Dominguez Hills

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WH D445
Carson, CA 90747

Revised September, 2007

# PREFACE

California State University Dominguez Hills (CSUDH) maintains an institutional commitment to basic and applied research, to dissemination of research results, and to creative activity in the visual and performing arts. Members of the faculty implement this commitment through the creation of new knowledge, the development of innovative teaching techniques, and the generation of programs responsive to student and community needs.

Much of this activity is facilitated by funding from external agencies. This handbook provides information about the policies and procedures involved in proposal preparation and grant administration. It is hoped that this information, combined with the support services of the Office of Research and Funded Projects (ORFP) and the CSUDH Foundation, will assist faculty in generating successful proposals that enhance the scholarly life of the campus community and lead to improvements in the educational process.

Many of the procedures outlined in this Handbook were developed by a Task Force on Grants and Contracts Administration and first enacted in September 1978. Technical revisions reflecting the current organizational structure of the university have been incorporated in this edition including those of Executive Order 890 issued by the Office of the Chancellor. The focus of this Handbook is on pre-award activities. Rules, regulations and procedures governing the expenditure of funds and other post-award activities can be found in the *Account Holders' Handbook* and the *Personnel Policy and Procedures Manual* published by the CSUDH Foundation.

The processes, procedures, and ORFP services identified in this handbook apply to grant and contract funds administered through the University and the CSUDH Foundation. It is important to note, however, that the Office of Research and Funded Projects will also assist faculty in obtaining individual awards such as fellowships that are paid directly to the individual and do not require administration by the institution.

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Revised – September, 2007

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# I. GRANT PROPOSAL PREPARATION

## 1. Principal Investigators

The planning of research projects and the preparation of proposals for submission to outside funding agencies are typically performed by employees of the University. This includes full-time and part-time faculty, adjuncts, and staff. On occasion, a visiting professor or researcher affiliated with the university may choose to serve as a principal investigator. Each project, whether research, curriculum development, continuing education, instruction, or community outreach must have a designated principal investigator (PI) who will see that the terms of the grant or contract are fulfilled. Students may also apply for grants through the University under the sponsorship of a faculty member (who is listed as the official PI and assumes overall responsibility for the project).

## 2. Locating a Funding Source

The Office of Research and Funded Projects is the resource to be used for determining possible sources of funds, providing assistance in grant proposal writing, and in budget preparation, establishing relationships within the University for necessary services, and acquainting faculty with external funding agency requirements. The CSUDH Foundation takes responsibility for administering the fiscal aspects of a project when an award is made.

When a faculty member has an idea relating to a possible proposal, she or he is encouraged to contact the Office of Research and Funded Projects (ORFP). The ORFP staff will assist in defining and conceptualizing the project and identifying appropriate funding agencies for the project. ORFP also provides ongoing information concerning other grant programs and requests for proposals that fall within a faculty member's specific academic area. A keyword database of faculty interests is maintained for this purpose. Any faculty member who has not completed a keyword survey form is encouraged to contact ORFP to be entered into the database.

## 3. Development of a Proposal for Submission

After the initial contact with ORFP, the Principal Investigator proceeds with preparation of the proposal. Initially, this may take the form of a concept paper or prospectus. In developing either a preliminary or final proposal, faculty members may obtain assistance from the Office of Research and Funded Projects during preparation of both the narrative and the budget. ORFP staff will read drafts, edit, or offer suggestions for organizing the document. The PI also must discuss the intended project with his or her college dean (or, in the case of staff, the appropriate administrative supervisor) to determine the potential impact of the proposed project on the college or administrative area.

Virtually all agencies now require electronic submission of proposals instead of paper copies. The Office of Research and Funded Projects serves as the gate keeper for access to electronic submission systems. Be sure that you give adequate warning

to ORFP if you intend an electronic submission. The submission may be submitted in an instant, but there is advance preparation required for all of the submission systems.

## 4. Budget

It is important that the Office of Research and Funded Projects be consulted during development of the budget section of a proposal. Unless the PI has specific reasons to do otherwise, ORFP staff will prepare budget documents. Faculty members should be aware that although salary reimbursement policies vary from agency to agency, they are generally made at the equivalent of the individual's actual university rate. Proposals may include requests for assigned time or released time from teaching, summer, and/or inter-session salary (maximum two months per year), and, in rare cases, overload (maximum 25%) for research activities conducted over and above a full teaching load during the academic year. Normally, the benefits associated with the salary are included in the budget request to the agency. If faculty on academic year appointments receive salary from a project during the summer, it is paid (based on annual salary rate) directly from grant funds by the CSUDH Foundation. Current information regarding salary and fringe benefit rates can be obtained from the Office of Research and Funded Projects.

Development of the project budget includes the determination of both direct and indirect costs. Direct costs are defined as those directly attributable to the specific project. Examples include: salaries and fringe benefits, supplies and services, travel, printing, and equipment. Indirect costs are those associated with maintaining the institutional infrastructure: facilities overhead, research administration, accounting support, and depreciation or use allowance. Indirect cost rates are determined as a result of a separate negotiation between the CSUDH Foundation and a federal agency. The CSUDH Foundation's standard negotiated rate is with the U.S. Department of Health and Human Services. For any contract or grant agreement, the University seeks recovery of full indirect costs unless the funding agency in question has a formal written policy limiting indirect costs. In that case, the applicable rate for that funding agency will be used. Any waiver of normal allowable indirect costs must be negotiated between the PI's dean and the executive director of the CSUDH Foundation. Principal Investigators may acquire information regarding current indirect cost rates from the Office of Research and Funded Projects or from the CSUDH Foundation.

If the budget includes funding for additional staff to support the project, it should be noted that any position for which an individual is not identified by name in the proposed budget must be filled in accordance with University and Foundation Equal Employment/Affirmative Action policies and procedures.

## 4.1. Costshare and Matching Funds

Definitions
Costsharing is a contribution of cash, services, or in-kind assets provided by the grantee institution or third-parties to the overall costs of a sponsored project. If costsharing is required by the funding agency, the level and type of contributed support are generally specified in program guidelines or application instructions.

Mandatory costshare is a specified amount required by statute, regulation or written policy.

Voluntary costshare are those commitments made beyond any mandatory levels of costshare.

Matching funds are required by statute generally as a specified percentage of program or project costs in order to be eligible for the sponsor's funding. This requirement may be stated either as a specified or minimum percentage of total allowable costs or a maximum sponsor percentage of participation in such costs (Examples: Applicant must provide an amount equal to the sponsor's funds -- a 50% or 1-1 match; Applicant must provide 20% of total project costs; Sponsor will provide funds not to exceed 80% of total project costs).

In-kind contributions will be only third-party contributions of services, goods or cash. Any contributions by the University will be considered cash costshare for the purposes of documentation and reporting.

## 4.2. Allowable Costs as Costshare

Depending on the program or agency, costshare commitments may be satisfied by providing cash, in-kind services or supplies, tuition waivers, faculty or staff time and effort devoted to the project, or waived facilities and administrative (indirect) costs. The proposal must specify the type of costshare, including individuals' names and percent of effort, the amounts, and the source of funds for costshare obligations. Allowable costshare must be for costs that comply with federal cost principles and award terms. They must be costs that are allocable, necessary and reasonable, and verifiable and accounted for in the institutional records.

Cash costshare can include dedicated dollars (such as for equipment purchase) from a CSUDH department or institute operating account, from another grant (non-federal grants, federal work-study funds, or another federal grant after prior approval obtained from the agency), or from other third-party sources (cash gifts or grants from individuals, industry, foundations, etc.) if not already committed to another project as costshare. It can also include donated CSUDH faculty or staff time that is already paid for by another non-federal account and the associated benefits and indirect costs on the CSUDH contributions. Indirect costs not chargeable to the grant when the program limits the applicable indirect rate may serve as cash contribution, as long as the agency allows the difference between the

limited rate and the institution's federal negotiated rate to be used as costshare. In-kind costshare is donated services and goods from any eligible third-party source; that is, services, supplies, equipment or other items purchased or donated by a non-University source but dedicated to and documented for the specific project. Volunteer services are eligible when the effort is tracked and fairly valued.

## 5. Campus Approval and Submission of Proposals

Most agencies place the legal responsibility for awards on the institution; therefore, it is the policy of the University that no proposal (including those for program funds from the CSU Chancellor's Office) be submitted without the full endorsement of appropriate representatives of the University. Before any proposal is forwarded to a potential funding agency, it must be reviewed and approved for consistency and compliance with school and institutional policies. These approvals are recorded on the CSUDH Proposal Approval form known as "the greensheet." Copies of the sheet are available from the ORFP, on the office website (www.csudh.edu/RF/r&fpro.htm), or in Appendix A of this handbook.. It is best to allow several working days for the completion of this approval process.

### 5.1 Issues addressed during campus approval:

If a proposed project involves the use of human subjects, live vertebrate animals, or hazardous materials, it must undergo review by the appropriate campus committee. Initial reviews, conducted under both federal regulations and campus policies, must be completed before the project can be funded. The University or CSUDH Foundation does not accept awards for, nor does it sponsor under its own auspices, research involving human subjects, animal subjects, or hazardous materials unless the research is given initial and continuing review. Information on the policies and procedures to be followed by the Principal Investigator in requesting the required review processes is available in the Office of Research and Funded Projects, on the ORFP website (www.csudh.edu/RF/r&fpro.htm) under "Compliance," or in the appendices to this handbook.

Any cost-sharing sources must be identified on the "greensheet;" and space and facilities commitments must be approved. Likewise, any significant financial or personal interests on the part of the principal investigator, his spouse, or dependent children that might compromise or appear to compromise the investigator's professional judgment in conducting or reporting research must be disclosed, and, where they occur, adjudicated in accordance with institutional policy. Additionally, the principal investigator must certify that they are not currently suspended, debarred, proposed for debarment, declared ineligible or voluntarily excluded from covered transactions by any Federal department or agency.

The principle of openness in research, including the freedom of access by all interested persons to the underlying data, processes and final results of research is of overriding importance. Accordingly, neither the University nor CSUDH Foundation enters into any agreement to carry out research if the grant or contract limits the right of the University to disclose the: (1) existence of the grant or

contract; (2) the general nature of the inquiry to be conducted; or (3) the identity of the sponsor.

Federal agencies require that copies of certain assurances be included with a proposal for funding. These include assurances that the institution provides a drug-free workplace, that the institution is not delinquent in any Federal debt, and related compliance issues. The Office of Research and Funded Projects will fill out these forms and will obtain the required institutional signatures.

### 5.2 Getting the Approval Signatures

To initiate the formal approval process, the Principal Investigator attaches a copy of the approval form ("greensheet") to a copy of the proposal and its budget. (If an electronic submission is planned, a print copy of the materials must be made for the approval process.) The PI completes and signs the approval form, ORFP will then obtain the signatures of the department or program Chair/Coordinator (if appropriate) and college dean (or other appropriate administrative supervisor). The proposal is then routed to secure approval signatures by additional university officials who examine the proposal for compliance with institutional policies. Under current campus policy, the Vice-President for Academic Affairs or designee provides the official signature for all project proposals submitted to external funding agencies. If a signature is required on the cover page of the proposal, it is normally that of the Vice President for Academic Affairs or designee, and ORFP will see that it is obtained. It should be noted, however, that the official applicant agency is the CSUDH Foundation (since it will be the agency administering the funds.) Once the proposal has the endorsement of the University, the Office of Research and Funded Projects notifies the Principal Investigator and submits the required number of copies to the funding agency or in the case of electronic submission, hits the "submit" button.

Some federal funding programs also require that the proposal be submitted to the designated California Single-Point-of-Contact (SPOC) for review; the Office of Research and Funded Projects will assist in complying with this requirement.

### 5.3 Compliance Issues Associated with Research Projects

The use of human or vertebrate animal subjects or biological agents such as recombinant DNA, in a research project requires special steps on the part of the investigator. The use of either human or animal subjects must be approved by the appropriate campus review committee. For human subjects, that is the IRB (Institutional Review Board) coordinated through the Office of Research and Funded Projects; for animal subjects, it is the Institutional Animal Care and Use Committee (IACUC) coordinated through the Department of Biology. Meeting schedules vary, so it is prudent to plan ahead. Research cannot begin without approvals. Biological agents must be registered with the institutional Biosafety Committee.

For human subjects it is also required that the investigator and any laboratory assistants or other staff who will conduct portions of the project be certified as having received appropriate training. There are several mechanisms for acquiring the training, but the most straightforward is an on-line course offered free through the National Institutes of Health. At the conclusion of the training, a certificate is printed out. That certificate must be sent or delivered to the Office of Research and Funded Projects so that the individual can be identified as eligible to conduct the project. The training program is available at the following website: http://CME.NCI.NIH.gov/

### 6. Project Negotiation

Submission of a proposal is the first step in the negotiation proceedings. The proposal details the work plan as well as level of effort, duration, and cost. Each of these items is acted on by funding agency personnel as part of their analysis and determination concerning support. Often, the funding agency requests a negotiation of the proposal budget and/or level of effort before making a final award decision. If a sponsoring agency requests either programmatic or budget revisions prior to approval of a grant or contract, the Principal Investigator should discuss the requests with the Office of Research and Funded Projects. Staff from the ORFP, working with the CSUDH Foundation, will assist the PI in making revisions within University policy and handling the direct negotiation with representatives of the funding agency.

## II. ADMINISTRATION OF GRANT/CONTRACT AWARDS

### 1. Notification of Agency Decision

When a project is funded, a "Notice of Award" is issued by the sponsoring agency and should be forwarded to the CSUDH Foundation. Unless special circumstances apply, the CSUDH Foundation is the recipient of the contract or grant and is responsible for the administration and financial records of all projects once funded. If the project involves a contract, the sponsor sends an Agreement to the CSUDH Foundation for execution. For purpose of later site visits by auditors, the original award notification is maintained in the files of the CSUDH Foundation. Additional copies should be kept by the Principal Investigator, Office of Research and Funded Projects, and the appropriate academic or administrative unit.

If a project is rejected, the Principal Investigator should immediately consult with the Office of Research and Funded Projects to obtain reviewer comments from the agency and to seek alternative sources of grant support. The process is often complex, requiring knowledge of agency technical requirements. Most funding agencies are open to discussing reasons for rejections and will suggest ways to improve prospects of future support. In some cases, the agency will suggest that the PI "revise and resubmit" the proposal. Similarly, the reasons for rejection may have nothing to do with the intrinsic quality or merit of the proposal content, but pertain

to other considerations, e.g. limited agency resources or submission of a proposal that is outside the agency's published guidelines.

## 2. Project Operation

Monies obtained through a grant or contract must be spent in accordance with the proposal and the applicable guidelines. The Principal Investigator will receive from the CSUDH Foundation a document containing the account number and other information related to the establishment of the account. The process of expending funds is initiated by the Principal Investigator. All expenditures must comply with: (1) the terms of the grant or contract; (2) policies and requirements of the funding agency; and (3) all University and CSUDH Foundation policies and procedures with respect to hiring of project personnel, financial commitments, and expenditure of funds. Details of the process are identified in the *Account Holder's Handbook* and the *Personnel Policy and Procedures Manual* published by the CSUDH Foundation. During operation of the project, the CSUDH Foundation provides monthly expenditure reports to the Principal Investigator and appropriate academic or administrative units for internal purposes in tracking the status of the external funds.

If, during the grant period, the Principal Investigator wishes to amend a contract or grant or adjust the project budget, the Office of Research and Funded Projects should be contacted to discuss the proposed changes. Staff at ORFP will determine, through consultation with the CSUDH Foundation, whether prior approval is required by the funding agency in order to initiate revisions. If it is required, the Principal Investigator contacts the funding agency and follows its procedures for requesting written authorization for the changes or the budget revisions. An amended contract or grant will be routed, along with an explanatory memorandum, to those units impacted by the change, e.g., academic affairs, financial affairs, or student affairs.

## 3. Reassigning Responsibilities of the Principal Investigator

In the case of an incumbent principal investigator's reassignment, resignation, incapacitation, or failure to perform duties adequately, the co-principal investigator shall assume responsibility of directing the grant or contract. In instances where a co-PI is not designated in the grant proposal or contract, the Academic Vice President or designee shall appoint a new PI to assume the duties and functions to assure project continuity and successful completion. Changes in PI status shall be reported to and approved by the funding agency.

## 4. Reporting Requirements

The Principal Investigator prepares all project interim progress and final reports required by the sponsoring agency prior to deadline. To assure progress toward the fulfillment of contract or grant requirements, copies of all reports are forwarded to the agency, appropriate academic or administrative units, the Office of Research and Funded Projects, and the CSUDH Foundation. CSUDH Foundation prepares fiscal

reports required by the sponsoring agency. Copies are forwarded to the Principal Investigator, sponsoring agency, and appropriate academic or administrative units.

## 5. Project Completion

Grant recipients should make every effort to fulfill all obligations under the terms of their grants. If the project is likely to run beyond the existing funding period, the PI should begin to seek new sources of funding 6-9 months before the existing funding period ends. If funds will be left over at the end of the funding periods, sponsoring agencies will often consider extending the grant period for a reasonable length of time (at no additional cost). However, most agencies require that a request be submitted a minimum of 45 days prior to the stated end date. The Office of Research and Funded Projects can assist the Principal Investigator in preparing the request and interpreting other agency requirements for project completion.

## 6. Retention of Records

All records of grants and contracts including proposals, award letters, and all reports, will be retained for a minimum of 3 years from the project completion date. Grant proposals which are not funded will be retained for a minimum of three years from the date of submission. After the retention period has ended, all proposals files will be shredded and discarded. Records which are deemed to have some historical value will be retained in the Office of Research and Funded Projects indefinitely. In those specific instances where a sponsor requires a longer term of record retention, the Office of Research and Funded Projects will retain records to meet the specific requirements of the funding agency.

# III. APPENDICES

## A. Approval Form (Greensheet)

**CSUDH PROPOSAL APPROVAL FORM**

**Project Director:** **Dept./College**

**Co-Director:** **Dept./College**

**Project Title:**

**Budget Period (# of years):**

**Funding Agency/Program:**

**Brief Project Summary**

**First Year Funding Request:**

| | Sponsor: | Cost-Share | Total |
|---|---|---|---|
| Direct Costs | $ | $ | $ |
| Indirect Costs | $ | $ | $ |
| Total Budget | $ | $ | $ |

Indirect Cost Rate and Base:

Cost-Sharing Required? ☐ Yes ☐ No

If yes, please complete the cost-share addendum

Proposal type: ☐ New ☐ Renewal ☐ Supplement ☐ Continuation ☐ Resubmission

Purpose: ☐ Research ☐ Training/Instructional ☐ Equipment ☐ Other

Sponsor Type: ☐ Federal ☐ State ☐ Corporation ☐ Foundation ☐ Other

***Note: If awarded, the recipient of the grant or contract shall be the CSUDH Foundation and not the project director, department or constituent unit.***

## Checklist

If "yes" box is checked, please provide an explanation of need and how any costs will be covered.

1. Human Subjects ☐ Yes ☐ No

   IRB Approval Date _____ Pending ☐

2. Vertebrate Animals ☐ Yes ☐ No

   IACUC Approval Date _____ Pending ☐

| | | | | |
|---|---|---|---|---|
| 3. Currently suspended, debarred or declared ineligible by any Federal Agency | ☐ | Yes | ☐ | No |
| 4. University Computing Facilities | ☐ | Yes | ☐ | No |
| 5. Purchase of Equipment | ☐ | Yes | ☐ | No |
| 6. Subcontract to Another Organization | ☐ | Yes | ☐ | No |
| 7. New/Revised Curriculum | ☐ | Yes | ☐ | No |
| 8. Additional Office/Space Needs (if yes, complete attachment) | ☐ | Yes | ☐ | No |
| 9. Facility Remodeling or Equipment Installation | ☐ | Yes | ☐ | No |
| 10. Radioactive Materials or Isotopes | ☐ | Yes | ☐ | No |
| 11. Recombinant DNA Technology | ☐ | Yes | ☐ | No |
| 12. Hazards and Carcinogens | ☐ | No | ☐ | No |
| 13. Scientific Diving Operations | ☐ | Yes | ☐ | No |
| 14. Compressed Gas and Air Cylinders | ☐ | Yes | ☐ | No |
| 15. Lasers | ☐ | Yes | ☐ | No |
| 16. Operation of a Medically Related Facility including handling of blood and human fluids | ☐ | Yes | ☐ | No |
| 17. Substances controlled by the U.S. Drug Enforcement Agency or the U.S. Food and Drug Administration | ☐ | Yes | ☐ | No |
| 18. Travel Outside of U.S. | ☐ | Yes | ☐ | No |

***An affirmative response to any item numbered 10-18 will prompt a project review by CSUDH Risk Management and Environmental Health and Safety.***

**Salary Requests**

CSUDH is required to request from all granting agencies full (actual) salary and benefit costs for faculty/employees working on a grant. Do the reimbursement costs listed in this grant reflect full (actual) costs? Yes ☐ No ☐

If no, a *Faculty/Employee Full Cost Reimbursement Waiver Request Form* must be completed and approved.

**Faculty Release Time/Overload Request**

Does this proposal request funds for faculty/staff release time or overload time? Yes ☐ No ☐

If yes, please note whether it is released time or overload and identify names, departments, percentage time or number of units and time period on the lines below.

_____

_____

_____

**Project Director** **Date**
(certifies accuracy of the proposal and Willingness to follow University and sponsor policies in the conduct of the project)

_____

**Department Chair** **Date**
(approves project and any department cost sharing)

_____

**Dean** **Date**
(approves project, school cost sharing and compatibility with school's policies)

_____

**Director, Research and Funded Projects** **Date**
(certifies the accuracy of the proposal and willingness to follow University and sponsor policies in the conduct of the project)

_____

**Vice-President for Administration And Finance** **Date**
(approves commitments of space and institutional funds)

_____

**Executive Director CSUDH Foundation** **Date**
(approves on behalf of Foundation, which acts as fiscal agent)

_____

**Dean, Graduate Studies and Research** **Date**
(approves project and cost-sharing arrangements)

## CSUDH Cost-Matching and Cost-Sharing Proposal Clearance Addendum

### I. Personnel Time and Effort Committed as Cost Share

Indicate the faculty/staff salary and fringe benefits committed as match to this project or research

| Name | WTU or % of full position | | Dollar Value | Time Period |
|---|---|---|---|---|
| | WTU | % | $ | |
| | WTU | % | $ | |
| | WTU | % | $ | |
| | WTU | % | $ | |
| | WTU | % | $ | |
| | WTU | % | $ | |
| | WTU | % | $ | |
| | WTU | % | $ | |
| | WTU | % | $ | |

### II. University Cash Match, i.e. from internal sources

Indicate any University cash match to this project or research

| Amount: | Time Period: |
|---|---|
| $ | |
| Name and signature/s of dean, vice-president or other authorized party ☟ | |
| Date: | |
| Date: | |
| Date: | |

## III. External Cash Match, i.e. from corporations, foundations or school districts

Indicate any external cash match to this project or research (attach any documentation of support)

| Amount | Time Period | Source |
|---|---|---|
| $ | | |
| Typed name and signature/s of University person/s developing the cash ✍ | | |
| Date: | | |
| Date: | | |

## IV. University In-Kind Cost-Share other than time and effort

Indicate the University In-Kind Contributions to this project or research (equipment, software, processing, supplies, materials, facilities, etc.)

| | | | |
|---|---|---|---|
| Description: | | | |
| Value (in dollars) | Number of Units | Total Value (in dollars) | Time Period |
| $ | | $ | |
| Description: | | | |
| Value (in dollars) | Number of Units | Total Value (in dollars) | Time Period |
| $ | | $ | |
| Description: | | | |
| Value (in dollars) | Number of Units | Total Value (in dollars) | Time Period |
| $ | | $ | |
| Typed name/s and signature/s of dean, vice-president or other authorized party ✍ | | | |
| Date: | | | |
| Date: | | | |
| Date: | | | |

## V. External In-Kind Cost-Share

Indicate the External In-Kind Contributions to this project or research (equipment, software, processing, supplies, materials and facilities)

| | | | |
|---|---|---|---|
| Description: | | | |
| Value (in dollars) | Number of Units | Total Value (in dollars) | Time Period |
| $ | | $ | |
| Description: | | | |
| Value (in dollars) | Number of Units | Total Value (in dollars) | Time Period |
| $ | | $ | |
| Description: | | | |
| Value (in dollars) | Number of Units | Total Value (in dollars) | Time Period |
| $ | | $ | |
| Description: | | | |
| Value (in dollars) | Number of Units | Total Value (in dollars) | Time Period |
| $ | | $ | |
| Description: | | | |
| Value (in dollars) | Number of Units | Total Value (in dollars | Time Period |
| $ | | $ | |
| Typed name and signature of University official responsible for verification of in-kind contributions ☟ | | | |
| Date: | | | |

**Space Needs Justification ***

| |
|---|
| **How will space be used?** |
| **Are additional fixtures or equipment needed?** |
| **How will space modification costs be covered?** |
| **What is the requested duration of space?** |

**** Please note that a Space Request Form should be submitted to the Space Allocation Committee***

**CALIFORNIA STATE UNIVERSITY, DOMINGUEZ HILLS**
**CONFLICT OF INTEREST DISCLOSURE FORM**

Investigator's Name: _____

Department/College: _____

Project Title: _____

_____

Proposed Funding Agency: _____

**I am disclosing the following significant financial interests related to the funding for this project (Responses should include the investigator, his/her spouse and any dependent children).**

Name of Entity: _____

Address of Entity: _____

Principal Type of Business: _____

| | | |
|---|---|---|
| Are you a director, officer, partner, trustee or employee of the entity? | ☐ Yes | ☐ No |
| Have you received in the last 12 months or expect to receive in the next 12 months salary, consulting fees and/or other payments in excess of $10,000 as an employee or agent of this entity? | ☐ Yes | ☐ No |
| Do you have an investment of $10,000 or more in this entity? | ☐ Yes | ☐ No |
| Do you hold an equity position of %5 or more in the entity? | ☐ Yes | ☐ No |
| Do you have an interest in any intellectual property rights belonging to the entity? | ☐ Yes | ☐ No |

If yes to the above, please attach a statement indicating your short or long term commitment of time and effort to be devoted to the outside project and the expected benefits to the outside entity, to CSUDH and to you. Include details of any financial arrangements pertaining to compensation or equity ownershipor other forms of economic value provided to you or any other immediate member of your family. Add any other relevant information that would contribute to an informed decision regarding the nature and management of the conflict. If you wish to suggest a strategy for managing the conflict or potential conflict, please do so.

**Investigator certification:**

- I agree to update this disclosure annually or sooner if new reportable significant financial interests emerge;
- I agree to cooperate in the development of a management plan to address any actual or potential conflict of interest identified in this disclosure and
- I agree to comply with any conditions or restrictions imposed by CSUDH to manage, reduce or eliminate actual or potential conflicts of interest.

Investigator's Signature: _____ Date: _____

(This form and related document should be filed with the Office of Research and Funded Projects, WH D-445)

## B. IRB Policy

### California State University, Dominguez Hills
### Institutional Review Board Policy

The United States Department of Health and Human Services Code of Federal Regulations Title 45, Part 46, states that the Institutional Review Board (IRB) shall establish "a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or cosponsored by the institution." In accordance with this mandate, the California State University, Dominguez Hills IRB has institutional responsibility for:

1. Assurance of protection of human subjects involved in research or related activities;

2. Assurance that the University fulfills its federally mandated and ethical obligations relative to the protection of human subjects; and

3. Maintenance of practices and procedures for protection of human subjects which are, at a minimum, in accord with applicable regulations of funding and regulatory agencies.

The IRB has the authority to review, approve, not approve, or require changes in research or related activities involving human subjects, as well as deal with issues of noncompliance. Officials of the institution may further review proposals, but "those officials may not approve the research if it has not been approved by an IRB (45CFR46.112)."

The Board is appointed by the President after consultation with various administrators. The membership composition of the Board is kept consistent with federal regulations and must include faculty representatives. Chairpersons, ex officio members, and community members of the Board are designated by the President. Board members with other than ex officio status normally shall have staggered three-year appointments. The Board reports to the President through the Associate Vice President for Academic Affairs and Dean of Graduate Studies. The Vice President for Academic Affairs serves as the designated institutional official on the United States Department of Health and Human Services Single or Multiple Project Assurances. The Office of Research and Funded Projects is responsible for support in managing individual proposal reviews; assisting in policy development, agency liaison, federal record keeping and reporting; handling allegations of noncompliance, and assisting the institution in responding to new federal initiatives affecting the ethical conduct of research.

Any undertaking in which a University administrator, faculty, staff, or student investigates and/or collects data on human subjects for research or related activities may be construed as "involving human subjects." It is the responsibility of each investigator to seek review by the Institutional Review Board for any proposed study involving human subjects prior to initiation of the project and collection of data. Also, it is the responsibility of each investigator to ensure that research is implemented and records maintained in accord with California State University, Dominguez Hills IRB procedures.

The specific responsibilities of the California State University, Dominguez Hills Institutional Review Boards are to:

1. Review all research projects (or related activities) using human subjects, that involve or are conducted by the university community.

2. Recommend appropriate action on these projects within the guidelines set forth by the applicable federal granting and regulatory agencies and California State University, Dominguez Hills IRB policy;

3. Review all proposed changes in previously approved research studies and recommend appropriate action on these changes within the guidelines set forth by the applicable federal granting and regulatory agencies and California State University, Dominguez Hills IRB policy;

4. Conduct continuing review of previously approved research projects at intervals appropriate to the degree of risk, but not less than once per year;

5. In accordance with federal guidelines, the IRB will handle reports of unanticipated problems and allegations of noncompliance concerning protection of human subjects regulations and, in cases where corrective action is needed, issue appropriate sanctions including but not limited to requesting minor changes, determining data collected cannot be used for publication, disqualifying investigators from conducting research involving human subjects at the University, and recommending to University administration that further administrative action be taken. "An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to subject (45CFR46.113)";

6. Advise appropriate University officials of current federal regulations or proposed changes in federal regulations pertaining to the protection of human subjects, and advise on University policy development and regulation changes which will best insure the rights and welfare of human research subjects;

7. Recommend to the President the constituencies to be represented on the Institutional Review Board; and

8. When participating in a cooperative project with another entity, enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements in accord with guidelines set forth by the applicable federal granting and regulatory agencies and California State University, Dominguez Hills IRB policy.

9. Provide an annual report on IRB activities to the Academic Senate and to the Associate Vice President for Academic Affairs or designee.

IRB meetings may be regularly scheduled or held upon call of the chairperson(s). Copies of the University's existing approved Federal Wide Assurance of Compliance with United States Department of Health and Human Services Regulations for Protection of Human Research Subjects and other educational materials are available in the Office of Research and Funded Projects. The complete Guidebook of CSUDH IRB Rules, Guidance, Standards, and Practices is available at the website, **http://www.csudh.edu/RF/IRB.Guidebook.pdf** .

## C. Assurance of Humane Care and Use of Laboratory Animals

**California State University, Dominguez Hills**
**Assurance Of Compliance**
**With**
**Public Health Service**
**Policy On Humane Care And**
**Use Of Laboratory Animals**

California State University, Dominguez Hills, hereinafter referred to as institution, hereby gives assurance that it will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

### I. APPLICABILITY

This Assurance is applicable to all research, research training, experimentation, biological testing, and related activities, hereinafter referred to as activities, involving live, vertebrate animals supported by the Public Health Service (PHS) and conducted at this institution, or at another institution as a consequence of the subgranting or subcontracting of a PHS-conducted or supported activity by this institution.

"Institution" includes the following branches and major components of California State University, Dominguez Hills: College of Arts & Humanities (CAH), College of Natural and Behavioral Sciences (CNBS), College of Health and Human Services (CHHS), College of Business Administration and Public Policy (CBAPP), and all departments and programs contained within these Colleges.

### II. INSTITUTIONAL POLICY

A. This institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

B. This institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."

C. This institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this institution will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance as well as all other applicable laws and regulations pertaining to animal care and use.

D. This institution has established and will maintain a program for activities involving animals in accordance with the *Guide for the Care and Use of Laboratory Animals*.

For more information concerning the use of Laboratory Animals in Research, check with the Office of Research & Funded Projects, WH D445, 310-243-3756.

## D. Reporting Possible Misconduct

**California State University Dominguez Hills**
POLICY AND PROCEDURES FOR DEALING WITH AND REPORTING POSSIBLE MISCONDUCT IN RESEARCH

# POLICY

Research and creative activity are becoming a major forces in the life of California State University Dominguez Hills (CSUDH). Faculty, staff and students are increasingly involved in projects designed to add to knowledge, provide students with the latest findings in a field, and/or explore solutions to problems in the world surrounding the institution. California State University Dominguez Hills is responsible for the integrity of the research and projects conducted at the institution or under its authority and recognizes the importance of ethical behaviors in the conduct of scholarly inquiry:

> Key elements in the process are the objective and accurate reporting of data accumulated in the course of experimentation, and verification of research findings to assure valid conclusions. In addition, generally-sanctioned standards of conduct and propriety, when followed, not only assure the integrity of the scientific professions, but engender public support for, and lend credibility to, the scientific endeavor as a whole.[1]

In addition to the university's own concern for the integrity of the process, federal regulations require that each institution that applies for or receives federal support for research must have explicit procedures for addressing incidents in which there are allegations of misconduct in research.

This policy and the set of procedures that follows incorporate the federal requirements into the institutional framework. They apply to all employees of CSUDH who are engaged in research and creative activities whether funded or not. They are designed to deal with any possible allegations of misconduct on the part of campus researchers while protecting the rights and privacy of both the complainant and the respondent. Furthermore, the document takes into account relevant provisions of the collective bargaining agreements between the CSU and its faculty and staff.[2]

# DEFINITIONS

"**Misconduct"** or **Misconduct in Science**" means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scholarly community for proposing, conducting, or reviewing research or reporting research results. It does not include honest error or honest differences in interpretations or judgments of fact.

"**Inquiry"** means information gathering and initial fact finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation.

**"Investigation"** means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred, and, if so, to determine the responsible person(s) and the seriousness of the misconduct.

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[1] Association of American Medical Colleges, Framework for Institutional Policies and Procedures to Deal with Misconduct in Research, Washington, DC, (March 1989), p.1.

[2] Agreement Between the Board of Trustees of the California State University and the California Faculty Association, Unit 3 – Faculty, 1998-2001; and California State Employees Association, Units 2,5,7, and 9, 1999-2001.

UNDERLYING PRINCIPLES

- The Association of American Medical Colleges identifies a set of "imperatives that should guide any institutional process for dealing with allegations of misconduct…"[3] They can be translated into a set of principles that meet federal requirements within the CSUDH environment:

- The university should ensure that the process used to resolve allegations of misconduct does not damage scholarship itself.

- The university should provide vigorous leadership in the pursuit and resolution of all charges.

- All parties should be treated with justice, fairness, and sensitivity for their reputations and vulnerabilities.

- Procedures should preserve the highest attainable degree of confidentiality compatible with an effective and efficient response to allegations of misconduct.

- The integrity of the process should be maintained by painstaking avoidance of real or apparent conflict of interest.

- Procedures should be as expeditious as possible leading to resolution of allegations in a timely manner.

- Pertinent facts and actions should be documented at each stage of the process.

The procedures set out in the following sections are based on these principles.

# PROCEDURES

## *Initial Allegations of Misconduct*

Formal allegations of misconduct in research must be submitted in writing to the Vice President for Academic Affairs. In order to determine whether the concerned activity falls within the definition of research misconduct, an individual may meet confidentially with the Vice President for Academic Affairs prior to preparation of the written document. If the circumstances described by the individual do not meet that definition, the Vice President for Academic Affairs will refer the individual to a dean, department chair, or other official responsible for oversight of the research in question. The Vice President for Academic Affairs will acknowledge receipt of the allegation in writing to the complainant.

If the Vice President for Academic Affairs has reason to believe that misconduct has occurred, but there is no formal written allegation, the Vice President may pursue the matter independently following the procedures outlined below.

In all cases, every effort should be made to maintain confidentiality for the protection of those who submit allegations of misconduct in science and for those against whom such allegations are made.

[3] Association of American Medical Colleges, op.cit., p.2.

## *Inquiry*

An inquiry is to be initiated by the Vice President for Academic Affairs within fifteen (15) days following receipt of an allegation of misconduct in research. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and the testimony of the respondent, the complainant, and key witnesses to determine whether there is sufficient evidence of possible misconduct to warrant a full investigation. The Vice President for Academic Affairs will have relevant physical evidence sequestered and will notify the respondent in writing when an inquiry is opened.

For purposes of the inquiry, the Vice President for Academic Affairs shall appoint a three-member Committee of Inquiry consisting of:

- The dean of the school of the individual against whom the allegation has been filed;
- One faculty member from the discipline in which the research is being conducted; and
- One faculty member from another discipline (selected in consultation with the Chair of the Academic Senate).

Substitutions or additions may be made if necessary to assure inclusion of members with appropriate seniority and knowledge who do not have a conflict of interest that would interfere with an objective review. If staff or students are involved, appropriate substitutions might include other staff or student representatives. The designated dean shall chair the Committee of Inquiry.

The Vice President for Academic Affairs shall charge the Committee of Inquiry, in writing, to conduct a discreet inquiry leading to a determination as to whether or not a formal investigation is warranted. Unless a written request for an extension has been approved by the Vice President for Academic Affairs and all parties have been notified, the Committee is expected to complete its inquiry within sixty (60) calendar days. The Committee's recommendations should be made to the Vice President for Academic Affairs and documented in writing. The respondent shall be provided a copy of the draft inquiry report for comment and rebuttal; the complainant, if identifiable, shall be provided with a summary of the inquiry findings for comment. Comments and rebuttal from all parties should be provided to the Committee of Inquiry within fourteen (14) calendar days of receipt of the draft report and will become part of the final inquiry report and record. The Vice President for Academic Affairs reviews the recommendations of the Committee of Inquiry and renders a decision. If there is to be no further action, the following reminder from the AAMC should be observed:

> If an allegation is found to be unsupported but has been submitted in good faith, no further formal action, other than informing all involved parties, should be taken. The proceedings of an inquiry, including the identity of the respondent, should be held in strict confidence to protect the parties involved. If confidentiality is breached, the institution should take reasonable steps to minimize the damage to reputations that may result from inaccurate reports.
>
> The institution should seek to protect the complainant against retaliation, including protecting anonymity whenever possible…[4]

If the decision is to move forward with an investigation, the respondent and the complainant shall be notified in writing, the report of the Committee of Inquiry along with supporting documentation shall be forwarded to the Committee of Investigation, and the agency sponsoring the research shall be notified. For Federally sponsored research, appropriate Federal authorities (e.g., ORI) should be notified at any stage of the inquiry or investigation if:

1. there is an immediate health hazard involved;
2. there is an immediate need to protect Federal funds or equipment;
3. there is an immediate need to protect the interest of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;
4. it is probable that the alleged incident is going to be reported publicly; or
5. the allegation involves a sensitive public health issue, e.g., a clinical trial; or
6. there is a reasonable indication of possible criminal violation or physical violence. In this instance, the institution must inform ORI within twenty-four (24) hours of obtaining that information, and local public safety or police should be contacted as appropriate.

[4] Ibid., p.8

## *Investigation*

The purpose of the investigation is to explore the allegations in detail, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. It will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. Any research records not previously sequestered during the Inquiry phase should be sequestered for use by the Committee of Investigation.

The Vice President for Academic Affairs shall appoint a Committee of Investigation within thirty (30) days of the decision to initiate an investigation. The Committee should consist of at least five individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations. These individuals may be researchers, administrators, subject matter experts, lawyers, or other qualified persons from inside or outside the institution. The appointments shall be made in consultation with the chair of the Academic Senate. The respondent shall be informed of the proposed Committee membership; if the respondent submits a written objection to any appointed member, the Vice President for Academic Affairs shall determine whether to replace the challenged member or expert with a qualified substitute. The Vice President shall designate one member of the Committee as chair.

The Vice President for Academic Affairs shall charge the Committee in writing to conduct a thorough investigation of the allegation. The charge will define the subject matter of the investigation, describe the allegations and related issues identified during the inquiry, provide definitions of research misconduct, and identify the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, the complainant, and key witnesses to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, to what extent, who was responsible, and its seriousness. The charge will further emphasize the need for confidentiality in all matters related to the investigation.

The investigation process will normally involve examination of all documentation, including such items as relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. Interviews of the respondent should be tape recorded or transcribed. All other interviews should be transcribed, tape recorded, or summarized. Summaries or transcripts should be provided to the interviewed party for comment or revisions and included as part of the investigation's file. While the function of the investigation is fact finding, the Committee and/or the respondent may choose to retain legal counsel for the purposes of advice.

If deemed necessary and recommended by the Committee of Investigation, interim administrative action may be taken to 1) protect human subjects involved in the research under review; 2) protect animal subjects in the research under review; or 3) prevent inappropriate expenditure of funds on the research under review.

The Committee of Investigation shall complete the investigation, and its report, within one-hundred twenty (120) calendar days from its first meeting date unless it finds that its work cannot reasonably be completed within that time, in which case the Committee may request a thirty (30) calendar day extension from the Vice President for Academic Affairs. The request should include the reasons for the delay, a progress report, an outline of remaining steps, and an estimated date of completion. The Vice President will forward the request to the Federal sponsoring agency, if appropriate. If the university plans to terminate the investigation for any reason without completing all relevant requirements, a report of such planned termination, including a description of the reasons for it, shall be made to appropriate Federal or private sponsors if the project is funded..

The Committee of Investigation's final report must document the extent to which, if at all, it has determined that misconduct has occurred. An investigation may result in one of several outcomes, including:

1. A finding of misconduct;
2. A finding that no culpable conduct was committed, but serious scientific or research errors were discovered;
3. A finding that no fraud, misconduct or serious scientific or research error was committed.

The report must identify the policies and procedures under which the investigation was conducted, a description of how and from whom information relevant to the investigation was obtained, and the basis for the findings. The report shall include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct; it may also recommend a course of action based on the findings.

A draft of the report shall be provided to the respondent, and a summary of the portions of the draft that address the complainant's role and opinions shall be provided to the complainant. The respondent and complainant will have ten (10) days to respond or comment. The respondent's comments will be attached to the final report; the report may be modified, as appropriate, based on the complainant's comments. Circulation of the draft report will be done under conditions of strictest confidentiality.

Based on a preponderance of the evidence, the Vice President for Academic Affairs will make a final determination whether to accept the investigation report, its findings, and any recommended institutional actions. If the Vice President's determination varies from that of the Committee of Investigation, the institution's letter transmitting the report to the funding agency must include a detailed explanation of the basis for rendering that decision. If no external funding agency is involved, the explanation is appended to the investigation file.

When a final decision on the case has been reached, the respondent and the complainant are notified in writing. The Vice President for Academic Affairs will determine a course of disciplinary action, keeping in mind the provisions of any applicable Collective Bargaining Agreement, and will determine whether law enforcement agencies, professional societies, licensing boards, editors of journals, collaborators of the respondent, or other relevant parties should be notified of the outcome of the case.

## *Other Considerations*

Termination of institutional employment or resignation prior to completion of the inquiry or investigation process will not preclude or terminate the misconduct procedures. If a respondent resigns and refuses to participate in the process after resignation, the committee will use its best effort to reach a determination, noting in its report the respondent's failure to cooperate.

If there is no finding of misconduct (and the cognizant Federal or other funding agency concurs), the university will undertake reasonable efforts to restore the respondent's reputation, including such possibilities as follow-up publicity if allegations were previously publicized or expunging all reference to the allegation from the respondent's personnel file.

Regardless of the Committee of Investigation's determination, the institution shall undertake reasonable efforts to protect the reputation of a complainant who made allegations in good faith and others who cooperated with the inquiry or investigation in good faith. If at any point, the Vice President for Academic Affairs has reason to believe that the allegations are not made in good faith, s/he may immediately determine appropriate administrative action against the complainant.

All records associated with the inquiry and investigation shall be maintained in secured files for a period of at least three years. They are to be made available to appropriate officials of the sponsoring agency upon request.

Originally issued as PM 89-19
Revised version issued as PM 01-08 (11/05/01)

## E. Conflict of Interest

**California State University, Dominguez Hills**
**Policy and Procedures for Dealing with Conflict of Interest in Research and Scholarly Activity**

In the area of conflict of financial interest or conflict of commitment, there are several sets of policies that apply to faculty and staff of California State University, Dominguez Hills (CSUDH). Officials and employees designated in the state's Conflict of Interest Code must comply with the policies governing the California Statement of Economic Interests. In addition, CSUDH upholds California State University system and institutional standards for outside professional activities in which its faculty and staff may become engaged. Information regarding system-wide policy on employment outside of the CSU is contained in Article 35 or the Unit 3 Collective Bargaining Agreement. CSUDH institutional policy with regard to outside consulting is framed as follows in the Faculty Handbook, section C:

> Consultation within her/his professional field is recognized as a legitimate activity for a faculty member of the University. Non-curricular activities of that nature should tend to improve and broaden the knowledge of the individual so engaged and bring prestige to the individual and the University. Private consulting service is proper for a member of the faculty to accept, but should not conflict with the performance of assigned academic duties.
>
> In all private consulting engagements, the client must be informed that the faculty member is acting as a private consultant and that the University is in no way a party to the contract. No official University stationery or forms shall be used in connection with such work, nor shall the name of the University be used in advertising.
>
> It is strongly urged that all employment outside the University by full-time members of the staff, other than that performed on an occasional basis only, be reported to the chairperson of the department and the dean of the school. Any questions on consulting services and incompatible activities should be discussed with the instructional dean of the school.

The above statements deal primarily with potential conflict of commitment or of educational mission. In keeping with Federal and State guidelines governing ethical practices in funded research and related scholarly activity, the following additional requirements related to financial interests apply:

### *CSUDH Policy*

Each investigator must disclose to the Vice President for Academic Affairs or a designee all significant financial interests of the investigator (including those of the investigator's spouse and dependent children) that would reasonably appear to be affected by the research or educational activities funded or proposed for external funding. In this connection, the term '**investigator**' means the principal investigator, co-principal investigator(s), and any other person at the institution who is responsible for the design, conduct, or reporting of the research or educational activities funded or proposed for funding. '**Significant financial interest**' means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria), equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties form such rights.). **Excluded from consideration are:**

1. Salary royalties or other remuneration from the applicant institution;
2. Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
3. Income from service on advisory committees or review panels for public or non-profit entities;
4. An equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than 5% ownership interest in any single entity;
5. Salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed $10,000 during the twelve month period.

Outside activities unrelated to university responsibilities and undertaken by faculty or staff members on personal time, regardless of whether compensated, are not subject to the above policies, unless the individual, while on personal time, engages in outside activities which create a potential conflict of financial interest.

A financial disclosure, if required under the definition above, must be provided at the time a proposal is submitted for external funding and updated annually, or more frequently if new reportable significant financial interests arise.

## *Procedures*

For activities that create a potential conflict of interest, the individual(s) must file a written disclosure containing the following information:

Name, department, and contact information;
Type of work or consulting to be provided;
Nature of the relationship in question;
Point of potential conflict of interest;
Short- or long-term commitment of time and effort to be devoted to the outside project;
Expected benefits to the outside entity, to the CSUDH employee, and to CSUDH;
Nature of any financial arrangements pertaining to compensation, including equity ownership and other forms of economic value provided to the university employee or any immediate member of the employee's family

The disclosure should be filed with the Office of Research and Funded Projects (ORFP) from where it will be forwarded to the Vice President for Academic Affairs. The Vice President for Academic Affairs, in consultation with the Associate Vice President for Faculty Affairs, and the Director of ORFP, shall determine whether a conflict of interest exists. A conflict exists when the reviewers reasonably conclude that a financial interest could potentially directly and significantly affect the design, conduct, or reporting of funded research. If such a determination is made, the reviewers will stipulate conditions or restrictions, if any, that should be imposed by the institution to manage, reduce or eliminate the potential conflict. A management plan might include one or more of the following strategies:

- Public disclosure of significant financial interests;
- Monitoring of research or scholarly activity by independent reviewers;
- Modification of the research plan;
- Disqualification from participation in the portion of research that would be affected by the significant financial interests;
- Divestiture of significant financial interests;
- Addition of a co-investigator who has no financial interest that would compromise the project;
- Termination or withdrawal of the proposed project.

If the reviewer(s) determine that imposing conditions or restrictions would be either ineffective or inequitable, and the potential negative impacts that might arise from the significant financial interest are outweighed by the interests of scientific progress, technology transfer, or the public health and welfare, then the reviewer(s) may allow the project to go forward without imposing conditions or restrictions.

The investigator shall be informed of the decision with respect to his or her disclosure within ten (10) working days of its receipt.

If an investigator refuses or neglects to adhere to a suggested management plan, the university will withdraw the proposal from the outside funding agency and will officially notify the funding agency's general counsel of the institution's inability to manage the conflict satisfactorily.

The Office of the Vice President for Academic Affairs shall maintain files of financial disclosures and all actions taken to resolve conflicts of interest for at least three years beyond the termination or completion of the grant to which they relate or until the resolution of any funding agency action involving those records, whichever is longer.

Issued as PM 01-09 (11/05/01)

## California State Requirement for Principal Investigators

A 700-U form must be filed by all persons employed by CSU who have principal responsibility for a research project if the project is to be funded or supported in whole or in part by a contract or grant from a non-governmental entity (e.g. corporation or foundation). These forms are submitted annually to the Human Resources office.

## F. Dealing With and Use of Recombinant DNA

**California State University Dominguez Hills**

POLICY AND PROCEDURES FOR DEALING WITH AND REPORTING ON THE USE OF RECOMBINANT DNA

# Policy

California State University Dominguez Hills (CSUDH), as an institution conducting activities or sponsoring research involving recombinant DNA, is governed by the U.S. Department of Health and Human Services/NIH *Guidelines for Research Involving Recombinant DNA Molecules*, May, 1999 as amended or superseded. The CSUDH Biosafety Committee shall serve as the institutional entity to assure that recombinant DNA molecules are used and registered in conformity with these Federal *Guidelines*.

## Membership

Based on the NIH *Guidelines,* the Biosafety Committee shall be comprised of at least five members selected so that they collectively have experience and expertise in recombinant DNA technology and possess the capability to assess the safety of recombinant DNA research and to identify any potential risk to public health or the environment. The Biosafety Committee shall include:

- Person(s) with expertise in recombinant DNA technology, biological safety, and physical containment;
- At least one member representing the laboratory technical staff;
- At least two community members not affiliated with the institution apart from their membership on this committee. Members may be retired faculty from CSUDH, current CSULB faculty, or from local laboratories.
- At least two members who are probationary or tenured members of the CSUDH faculty.
- At least one person knowledgeable about University commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment;
- The Director, Office of Research and Funded Projects, in an *ex officio* capacity.
- The Director of Environmental Health and Occupational Safety, serving as chair.

On any occasion in which the institution participates in or sponsors projects that involve experiments or conditions outlined in NIH *Guidelines*, Appendix P and Appendix Q, (utilizing plants or animals, respectively), recombinant DNA research at levels BL3, BL4, or on a Large Scale (greater than 10 liters), or involving human subjects, the institution will add additional committee members to provide necessary expertise to insure that all relevant safety issues are addressed. (*Guidelines*, Section IV-B-2-a-(1).

Members of the Biosafety Committee shall be appointed by the Vice President for Academic Affairs for terms of two years, except for community members whose terms shall be for no less than one year. Members may be reappointed for additional terms. No members may review research or other activities in which they are involved or have a direct financial interest.

## Responsibilities

All members of the CSUDH community who use recombinant DNA must comply with the NIH *Guidelines for Research Involving Recombinant DNA Molecules* as indicated in the sections identified below (or their subsequent counterparts or amendments):

- For work that falls under *Guidelines*, Sections III-A, III-B, and III-C, depending on the category, specific NIH approvals may be required in addition to institutional approval. The Principal Investigator must submit a registration document to the Biosafety Committee for institutional approval well in advance of initiating the experiment to allow for forwarding.
- For work conducted under *Guidelines*, Section III-D, the Principal Investigator must submit a registration document to the Biosafety Committee for approval prior to initiating the experiment.
- For experiments that fall under Section III-E, registration may take place at the time of initiation of the work.

- Work that falls under Section III-F is exempt from the NIH *Guidelines* ; it must meet institutional registration requirements, but does not require annual updating.

The Biosafety Committee will assess the level of containment required by the *Guidelines* for the proposed activities and will make an assessment of the facilities, procedures, practices, training, and expertise of the personnel involved.

## A Principal Investigator is responsible for compliance with the Guidelines by:

- Determining whether experiments are covered by the Guidelines; if they are, seeking appropriate and timely registration and/or Biosafety Committee approvals;
- Reporting any significant problems, violations, or research-related accidents or illnesses to the Biosafety Committee;
- Acquiring and maintaining adequate training in good microbiological techniques;
- Adhering to campus emergency plans or procedures for handling accidental spills or personnel contamination;
- Instructing and training laboratory staff in appropriate practices and microbiological techniques and making available the protocols that describe potential biohazards and the precautions to be taken.
- Supervising safety performance, ensuring the integrity of physical and biological containment levels, and correcting any work errors and conditions that might result in the release of Recombinant DNA materials.
- Complying with shipping requirements for recombinant DNA molecules, if appropriate;
- Submitting information to NIH/OBA for certification of any new host-vector systems;
- Submitting appropriate petitions to the NIH Office of Biotechnology Activities for proposed exemptions to the *Guidelines* and for approval to conduct experiments that require case-by-case review or specialized containment procedures.
- Identifying R-DNA use on the “greensheet” form circulated as part of the approval process for any proposals to external funding agencies.

## Reporting Requirements

- The chair of the Biosafety Committee shall notify applicants and the Director, Office of Research and Funded Projects, of the result of Biosafety review of registration documents and petitions, including instructions concerning the maintenance of appropriate containment levels per the NIH *Guidelines*.
- All approved users of recombinant DNA molecules shall immediately report to the chair of Biosafety Committee, RM/EHOC, and the Director of Research and Funded Projects any significant problems, violations, accidents or unexpected research results relating to the hazard inherent in the use of recombinant DNA molecules.
- The chair of the Biosafety Committee shall report on the committee’s activities annually to the Vice President for Academic Affairs.
- The Director, Office of Research and Funded Projects, shall make all reports to the NIH Office of Biotechnology Activities that are required by the *Guidelines*.

This policy shall be carried out through the procedures designed and maintained by the Office of Environmental Health and Occupational Safety on behalf of the Biosafety Committee.

Issued as PM 01-10 (11/5/01)

# Recombinant DNA Project Registration Instructions

The Biosafety Committee monitors the use of recombinant DNA at California State University, Dominguez Hills. All recombinant DNA projects require registration with the CSUDH Biosafety Committee.

**Projects that require registration:**

Projects that involve a living recombinant organism require registration with the CSUDH Biosafety Committee. Projects that require registration include those in which the only recombinant activity is the growing of plasmid in *E. coli* to make probes, the use of transgenic or knock-out animals, and experiments in which genes are cloned for site-directed mutagenesis. All (non-exempt, see below) projects will be initially reviewed by the Biosafety Committee and shall be updated whenever there is a change in procedure and personnel. In addition, projects will be updated and reviewed annually by the Office of Risk Management/Environmental Health & Occupational Safety (RM/EHOS).

Projects that do not involve living recombinants, e.g. the use of PCR and/or oligonucleotides alone, do not require registration.

**Exempt projects:**

The RM/EHOS office will review all projects and determine which projects are exempt and which require Biosafety Committee review. Exempt projects will require initial registration only, not annual updating. The RM/EHOS will notify you if your project is determined to be exempt.

**Completing the form:**

**Location of the project**: This information will be used to determine if the facility meets any special requirements to complete the project safely.

**Animal use**: The IACUC number is required if animals are used in conjunction with a recombinant DNA project.

**Biological agent use**: Complete this box if any infectious or regulated biological agents are used in the project. If so, please complete the bio-agent form also.

**Isotope use**: Complete this box if radioactive materials are used in the project.

**Purpose**: Use one sentence to outline the purpose of the project.

**Technical description of the project**: Describe the project to give the Biosafety Committee reviewers an understanding of the project.

If using viral vectors, mention the virus upon which the vector is based. List the amount of vector to be applied to cells or animals and the concentration used.

If applying recombinant virus or microorganisms to animals, list the amount and concentration of the vector or organism to be applied. Describe the application to the animal, i.e. injection, nasal application, applied through a cannula, etc. List any safety factors that you have already considered, like the use of blunt or self-sheathing needles or the use of a nasal inhalation containment device.

If using animals, describe the incubation period and what will be harvested or observed in the animal at the conclusion of the incubation period.

Describe the reason for using the specific genes and vectors, what outcome is expected, and what will be analyzed and/or measured.

**Deliberate expression of genes**: Answer yes or no. The information is used in conjunction with the NIH Guidelines to assess the appropriate containment level.

**Production of toxins**: Answer yes or no. The information is used in conjunction with the NIH Guidelines to assess the appropriate containment level.

**Vectors**: Please list vectors by name (e.g. pUC 18, pBS KS+, pTRUF-11) that will be used in the project. For vectors that are not commonly used or commercially available, please include a map detailing the regions of interest. The map may be hand drawn or a photocopy from a research article. The information is used to assess the appropriate containment level for each project.

**Strains**: List by strain name (e.g. HB101, JM109, 293T cells) any *E. coli*, other bacterial, yeast, insect, tissue culture, packaging, or other cells used for cloning, production, or expression in the project.

**Genes**: List the name of the nucleic acid sequence, gene, or protein that it encodes (green fluorescent protein, *Lac*Z, DNA binding protein). For unknown genes, list the putative function. Please also list the source of DNA (human, murine, maize, *Drosophila*, etc.).

**Bio-safety level and NIH Guideline citation**: Use the web site http://www4.od.nih.gov/oba to find the NIH Guidelines online. Alternatively, leave this section blank and the RM/EHOS office will complete it for you.

**Health Surveillance**: Not all projects require health surveillance. Check the Agent List (attached) for use of biological agents that require health surveillance. For example, the use of vaccinia vectors or poliovirus may require immunization, the use of HIV may require testing and serum banking, and the use of *Mycobacterium tuberculosis* may require annual TB skin tests.

**Personal Assurance Statement**: All personnel, including other faculty, who work on a particular project must sign that they understand and will abide by the NIH Guidelines for Recombinant DNA Research. The Principal Investigator shall sign the statement assuring that all personnel will be trained and that the PI is responsible to ensure compliance with the guidelines.

Biosafety Committee Chair signature: Rarely, the Biosafety Committee Chair will be required to sign for a particular project. The CSUDH RM/EHOS will secure this signature.

**Biological Safety Officer signature**: In some cases, the RM/EHOS will sign or otherwise designate that a facility is in compliance with the NIH Guidelines.

For additional information, please contact the CSUDH Risk Management / Environmental Health & Occupational Safety, at 243-3995.

# R-DNA

CSUDH Document of Registration

RM/EHOS

# _____

Principal Investigator: _____ PI's Title: _____

Department: _____ Address/Box: _____

Phone: _____ Email: _____

Project Title: _____

Grant #'s covered (optional) _____

| | |
|---|---|
| 1. Location of project<br>Project bldg.:_____<br>Project room:_____ | 2. Animal Use ☐ Yes ☐ No<br>IACUC#:_____<br>Rooms animals housed:_____ |
| 3. Biological Agent Use ☐ Yes ☐ No<br>Bio-Safety Office approval date:_____ | 4. Isotope Use ☐ Yes ☐ No<br>RCC Approval date: _____ |

5. Purpose of the Project (one sentence):

6. Technical description of project (use attachment if necessary):

7. Will you attempt deliberate expression of a gene? ☐ Yes ☐ No

8. Will you use or produce any toxins? ☐ Yes ☐ No

| 9. Vectors | 10. Strains (bacterial, yeast, cell lines) | 11. Genes (names of gene or name of protein it encodes) |
|---|---|---|
| | | |

| |
|---|
| 12. Bio-Safety Level and NIH Guideline Citation |
| 13. Health Surveillance |

14. The undersigned individual(s) will be involved in the experimentation described above. They are familiar with and agree to abide by the current NIH Guidelines.

| Name (Please Type or Print) | Signatures | Date |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

I attest to the fact that these individuals are properly trained in the area of recombinant DNA experimentation. Furthermore, I agree to comply with the NIH requirements pertaining to shipment and transfer of recombinant DNA materials. I am familiar with and agree to abide by the provisions of the current NIH Guidelines and other specific NIH instructions pertaining to the proposed project. The information above is accurate and complete.

Principal Investigator Date

15. (If required) I certify that the Biosafety Committee has reviewed the proposed project for recombinant DNA experiments and has found to be in compliance with the NIH Guidelines and other specific NIH instructions pertaining to the project.

Biosafety Committee Chairperson Date

16. The indicated sites have been inspected and are in compliance with the NIH Guidelines.

RM/EHOS Date

# Biological Agent

CSUDH
RM/EHOS

Document of Registration

# _____

Principal Investigator: _____ PI's Title: _____

Department: _____ Address/Box: _____

Phone: _____ Email: _____

Project Title: _____

Grant #'s covered (optional) _____

| | |
|---|---|
| 1. Location of project<br>Project bldg.:_____<br>Project room:_____ | 2. Animal Use ☐ Yes ☐ No<br>IACUC#:_____<br>Rooms animals housed:_____ |
| 3. R-DNA Use ☐ Yes ☐ No<br>Biosafety Committee approval date: _____ | 5. Isotope Use ☐ Yes ☐ No<br>RCC approval date: _____ |
| 5. Biological Agents<br>**list agents** **bio-safety level** | |
| 6. Safety Procedures<br>personal protective equipment: _____<br>method of inactivation of agent: _____<br>disinfection of surfaces procedure: _____ | |
| 7. Safety Equipment<br>bio-safety cabinet ☐ Yes ☐ No<br>model: _____<br>location: _____<br>certification date: _____ | autoclave available: ☐ Yes ☐ No<br>location: _____<br>monitored: ☐ Yes ☐ No |

8. Description of Project:

9. The undersigned individual(s) will be involved in the experimentation described above. They are familiar with and agree to abide by the current CSUDH guidelines.

| Name (Please Type or Print) | Signatures | Date |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

I attest to the fact that the above named individuals are properly trained in this area of experimentation.

Principal Investigator Date

10. The indicated sites have been inspected and are in compliance with the CSUDH guidelines.

RM/EHOS Date

# Acute Toxin

CSUDH
RM/EHOS

Document of Registration

# _____

Principal Investigator: _____ PI's Title: _____

Department: _____ Address/Box: _____

Phone: _____ Email: _____

Project Title: _____

Grant #'s covered (optional) _____

1. Location of project: Building _____ Room _____

2. Purpose of research:

3. Name of toxin: _____

   LD50: _____ mouse: ☐ rat: ☐ other: ☐

4. Quantity on hand: _____

   (amount of material should be kept to a minimum)

5. Toxins are required to be kept in locked cabinets or freezers. Is this being done?

   ☐ Yes ☐ No

6. Please outline the safety practices being utilized by the staff during the conduct of the project.

7. How is the compound inactivated/disposed of?

8. We are familiar with the preceding information and have been trained regarding emergency procedures in the event of an accident.

| Name (Please Type or Print) | Signatures | Date |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

I certify that this information is complete and correct.

Principal Investigator Date

9. The indicated sites have been inspected and are in compliance with CSUDH guidelines.

RM/EHOS Date

# G. Biological Waste Disposal Policy

This policy is intended to provide guidance and insure compliance with the NIH/CDC guidelines

**Infectious/potentially infectious/R-DNA**
a) human pathogens
b) animal pathogens
c) plant pathogens
d) recombinant DNA
e) human and primate blood, blood products and other body fluids
f) human and primate tissue
g) any material containing or contaminated with any of the above (test tubes, needles*, syringes, tubing, culture dishes, flasks, etc.)

**This waste must be inactivated prior to disposa**l. The preferred method is steam sterilization (autoclaving), although chemical inactivation or incineration may be appropriate in some cases. Storage of non-inactivated waste is restricted to within the generating laboratory. The material may not be stored longer than 24 hours prior to inactivation.

## Regulated Biological Materials

Agents, such as plant pathogens or exotic microorganisms, that are regulated by federal or state agencies (USDA/APHIS, EPA, FDA, DPI, etc.) shall be registered with the RM/EHOS by submission of a photocopy of the permit and permit conditions that have been granted by that agency. No special form is required unless the agent fits into one of the first three categories.

## Agents List

The following agents have been listed according to the most appropriate Biological Safety Level to be used. The list presented below is based upon the risk groups given in Appendix B of the March 1996 *Guidelines for Research Involving Recombinant DNA Molecules* (NIH Guidelines), the agent summary statements in the CDC/NIH publication, *Biosafety in Microbiological and Biomedical Laboratories (BMBL*), 3 rd edition (1993), guidance from state and local regulatory agencies, and recommendations of the CDC.
Please note that Biological Safety Levels are not inherent to an agent but are performance recommendations and should be chosen after a risk assessment is completed.
A proper risk assessment takes into account the characteristics of the agent involved, the activities to be performed, and the environment in which the work will be completed. Therefore, certain agents may be used at different Biological

Safety Levels depending upon the circumstances. For instance, human clinical

samples from HIV-positive patients may be safely handled at BSL-2. Growth of HIV in culture should be performed under BSL-3 containment. Biological Safety Levels may be higher or lower than what is given below for a particular agent depending upon the circumstances of its use.

The RM/EHOS reviews all projects involving recombinant DNA, infectious disease agents, and agents of concern to livestock and agriculture and will assist you in the risk assessment process. Once the Biosafety Committee and/or the RM/EHOS assigns a Biological Safety Level, it must be adhered to unless new information to warrant a change, in most cases from peer-reviewed literature, is provided. The Biosafety Committee and/or RM/EHOS will review the literature and make an adjustment, if warranted.

## Biological Safety Level 1 (BSL-1)

Agents that are not associated with disease in healthy adult humans, are of minimal potential hazard to laboratory personnel, and of minimal potential hazard to the environment may be used at BSL-1. Agents that may be used at BSL-1 include *Lactobacillus* spp., asporogenic *Bacillus subtilis* or *Bacillus licheniformis*, *Escherichia coli*-K12 (cloning strains), Baculoviruses, and adeno-associated virus types 1 through 4. Those agents not listed under Biological Safety Levels 2, 3 and 4 are not automatically or implicitly classified in BSL-1; a risk assessment must be conducted based on the known and potential properties of the agents and their relationship to agents that are listed.

## Biological Safety Level 2 (BSL-2)

Agents to be used at BSL-2 are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available. They are of moderate potential hazard to laboratory personnel and/or the environment.

**BSL-2 Bacterial Agents Including *Chlamydia***

- *Acinetobacter baumannii* (formerly *Acinetobacter calcoaceticus)*
- *Actinobacillus*
- *Actinomyces pyogenes* (formerly *Corynebacterium pyogenes)*
- *Aeromonas hydrophila*
- *Amycolata autotrophica*
- *Archanobacterium haemolyticum* (formerly *Corynebacterium haemolyticum)*
- *Arizona hinshawii* - all serotypes
- *Bacillus anthracis*
- *Bartonella henselae, B. quintana, B. vinsonii*
- *Bordetella including B. pertussis*
- *Borrelia recurrentis, B. burgdorferi*
- *Burkholderia* (formerly *Pseudomonas* species) except those listed under BSL-3
- *Campylobacter coli, C. fetus, C. jejuni*
- *Chlamydia psittaci, C. trachomatis, C. pneumoniae*
- *Clostridium botulinum, Cl. chauvoei, Cl. haemolyticum, Cl. histolyticum, Cl. novyi, Cl. septicum, Cl. tetani*
- *Corynebacterium diphtheriae, C. pseudotuberculosis, C. renale*
- *Dermatophilus congolensis*
- *Edwardsiella tarda*
- *Erysipelothrix rhusiopathiae*
- *Escherichia coli* - all enteropathogenic, enterotoxigenic, enteroinvasive and strains bearing K1 antigen, including *E. coli* O157:H7

- *Haemophilus ducreyi, H. influenzae*
- *Helicobacter pylori*
- *Klebsiella* - all species except *K. oxytoca* (BSL-1)
- *Legionella* including *L. pneumophila*
- *Leptospira interrogans* - all serotypes
- *Listeria*
- *Moraxella*
- *Mycobacterium* (except those listed under BSL-3) including *M. avium complex, M. asiaticum, M. bovis* BCG vaccine strain*, M. chelonei, M. fortuitum, M. kansasii, M. leprae, M. malmoense, M. marinum, M. paratuberculosis, M. scrofulaceum, M. simiae, M. szulgai, M. ulcerans, M. xenopi*
- *Mycoplasma, except M. mycoides and M. agalactiae* which are restricted animal pathogens
- *Neisseria gonorrhoea, N. meningitidis*
- *Nocardia asteroides, N. brasiliensis, N. otitidiscaviarum, N. transvalensis*
- *Rhodococcus equi*
- *Salmonella* including *S. arizonae, S. cholerasuis, S. enteritidis, S. gallinarum-pullorum, S. meleagridis, S. paratyphi,* A, B, C, S. *typhi, S. typhimurium*
- *Shigella* including *S. boydii, S. dysenteriae, type 1, S. flexneri, S. sonnei*
- *Sphaerophorus necrophorus*
- *Staphylococcus aureus*
- *Streptobacillus moniliformis*
- *Streptococcus* including *S. pneumoniae, S. pyogenes*
- *Treponema pallidum, T. carateum*
- *Vibrio cholerae, V. parahemolyticus, V. vulnificus*
- *Yersinia enterocolitica*

**BSL-2 - Fungal Agents**

- *Blastomyces dermatitidis*
- *Cladosporium bantianum, C. (Xylohypha) trichoides*
- *Cryptococcus neoformans*
- *Dactylaria galopava (Ochroconis gallopavum)*
- *Epidermophyton*
- *Exophiala (Wangiella) dermatitidis*
- *Fonsecaea pedrosoi*
- *Microsporum*
- *Paracoccidioides braziliensis*
- *Penicillium marneffei*
- *Sporothrix schenckii*
- *Trichophyton*

**BSL-2 - Parasitic Agents**

- *Ancylostoma* human hookworms including *A. duodenale, A. ceylanicum*
- *Ascaris* including *Ascaris lumbricoides suum*
- *Babesia* including *B. divergens, B. microti*
- *Brugia* filaria worms including *B. malayi, B. timori*
- *Coccidia*
- *Cryptosporidium* including *C. parvum*
- *Cysticercus cellulosae* (hydatid cyst, larva of *T. solium)*
- *Echinococcus* including *E. granulosis, E. multilocularis, E. vogeli*
- *Entamoeba histolytica*
- *Enterobius*
- *Fasciola* including *F. gigantica, F. hepatica*
- *Giardia* including *G. lamblia*
- *Heterophyes*

- *Hymenolepis* including *H. diminuta, H. nana*
- *Isospora*
- *Leishmania* including *L. braziliensis, L. donovani, L. ethiopia, L. major, L. mexicana, L. peruvania, L. tropica*
- *Loa loa* filaria worms
- *Microsporidium*
- *Naegleria fowleri*
- *Necator* human hookworms including *N. americanus*
- *Onchoerca* filaria worms including, *O. volvulus*
- *Plasmodium* including simian species, *P. cynomologi, P. falciparum, P. malariae, P. ovale, P. vivax*
- *Sarcocystis* including *S. sui hominis*
- *Schistosoma* including *S. haematobium, S. intercalatum, S. japonicum, S. mansoni, S. mekongi*
- *Strongyloides* including *S. stercoralis*
- *Taenia solium*
- *Toxocara* including *T. canis*
- *Toxoplasma* including *T. gondii*
- *Trichinella spiralis*
- *Trypanosoma* including *T. brucei brucei, T. brucei gambiense, T. brucei rhodesiense, T. cruzi*
- *Wuchereria bancrofti* filaria worms

**BSL-2 - Viruses**

Adenoviruses, human - all types

Alphaviruses (Togaviruses) - Group A Arboviruses

- Eastern equine encephalomyelitis virus
- Venezuelan equine encephalomyelitis vaccine strain TC-83
- Western equine encephalomyelitis virus

Arenaviruses

- Lymphocytic choriomeningitis virus (non-neurotropic strains)
- Tacaribe virus complex
- Other viruses as listed in the *BMBL*

Bunyaviruses

- Bunyamwera virus
- Rift Valley fever virus vaccine strain MP-12
- Other viruses as listed in the *BMBL*

Calciviruses

Coronaviruses

Flaviviruses (Togaviruses) - Group B Arboviruses

- Dengue virus serotypes 1, 2, 3, and 4
- Yellow fever virus vaccine strain 17D
- Other viruses as listed in the *BMBL*

Hepatitis A, B, C, D, and E viruses

Herpesviruses - except *Herpesvirus simiae* (Monkey B virus), BSL-4

- Cytomegalovirus
- Epstein Barr virus
- Herpesvirus ateles
- Herpesvirus saimiri
- *Herpes simplex* types 1 and 2
- *Herpes zoster*
- Human herpesvirus types 6 and 7
- Marek's disease virus
- Murine cytomegalovirus

• Pseudorabies virus
Orthomyxoviruses
• Influenza viruses types A, B, and C
• Other tick-borne orthomyxoviruses as listed in the *BMBL*
Papovaviruses
• All human papilloma viruses
• Bovine papilloma virus
• Polyoma virus
• Shope papilloma virus
• Simian virus 40 (SV40)
Paramyxoviruses
• Newcastle disease virus
• Measles virus
• Mumps virus
• Parainfluenza viruses types 1, 2, 3, and 4
• Respiratory syncytial virus
Parvoviruses
• Human parvovirus (B19)
Picornaviruses
• Coxsackie viruses types A and B
• Echoviruses - all types
• Polioviruses - all types, wild and attenuated
• Rhinoviruses - all types
Poxviruses
• vaccinia
• all types except Monkeypox virus (BSL-3) and restricted poxviruses including Alastrim, Smallpox, and Whitepox (restricted to the CDC, Atlanta, GA)
Reoviruses - all types including Coltivirus, human Rotavirus, and Orbivirus (Colorado tick fever virus)
Retroviruses
• Avian leukosis virus
• Avian sarcoma virus
• Bovine leukemia virus
• Clinical samples from HIV-positive patients
• Feline immunodeficiency virus
• Feline leukemia virus
• Feline sarcoma virus
• Gibbon leukemia virus
• Mason-Pfizer monkey virus
• Mouse mammary tumor virus
• Murine leukemia virus
• Murine sarcoma virus
• Rat leukemia virus
**NOTE:** Murine Retroviral Vectors
Murine retroviral vectors to be used for human transfer experiments (less than 10 liters) that contain less than 50% of their respective parental viral genome and that have been demonstrated to be free of detectable replication competent retrovirus can be maintained, handled, and administered, under BL1 containment.
Rhabdoviruses
• Rabies virus - all strains
• Vesicular stomatitis virus - laboratory adapted strains ONLY including VSV-Indiana,

San Juan, and Glasgow
Togaviruses (see Alphaviruses and Flaviviruses)
• Rubivirus (rubella)

## Biological Safety Level 3 (BSL-3)

Agents to be used at BSL-3 are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available.

**BSL-3 - Bacterial Agents Including Rickettsia**

• *Bartonella*
• *Brucella* including *B. abortus, B. canis, B. suis*
• *Burkholderia (Pseudomonas) mallei, B. pseudomallei*
• *Coxiella burnetii*
• *Francisella tularensis*
• *Mycobacterium bovis* (except BCG strain, BSL-2), *M. tuberculosis*
• *Pasteurella multocida* type B -"buffalo" and other virulent strains
• *Rickettsia akari, R. australis, R. canada, R. conorii, R. prowazekii, R. rickettsii, R, siberica, R. tsutsugamushi, R. typhi (R. mooseri)*
• *Yersinia pestis*

**BSL-3 - Fungal Agents**

• *Coccidioides immitis* (sporulating cultures; contaminated soil)
• *Histoplasma capsulatu*m, *H. capsulatum* var.. *duboisii*

**BSL-3 - Parasitic Agents**

None

**BSL-3 - Viruses and Prions**

Alphaviruses (Togaviruses) - Group A Arboviruses
• Semliki Forest virus
• St. Louis encephalitis virus
• Venezuelan equine encephalomyelitis virus (except the vaccine strain TC-83 is BSL-2)
• Other viruses as listed in the *BMBL*
Arenaviruses
• Lymphocytic choriomeningitis virus (LCM) (neurotropic strains)
• Flexal
Bunyaviruses
• Hantaviruses including Hantaan virus
• Rift Valley fever virus
Flaviviruses (Togaviruses) - Group B Arboviruses
• Japanese encephalitis virus
• Yellow fever virus
• Other viruses as listed in the *BMBL*
Poxviruses
• Monkeypox virus
Prions
• Transmissible spongioform encephalopathies (TME) agents, Creutzfeldt-Jacob disease and kuru agents (see *BMBL* for specific containment instruction)
Retroviruses
• Human immunodeficiency virus (HIV) types 1 and 2
• Human T cell lymphotropic virus (HTLV) types 1 and 2
• Simian immunodeficiency virus (SIV)
Rhabdoviruses
• Vesicular stomatitis virus

## Biological Safety Level 4 (BSL-4)

Agents to be used at BSL-4 are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.

**BSL-4 - Bacterial Agents**

None

**BSL-4 - Fungal Agents**

None

**BSL-4 - Parasitic Agents**

None

**BSL-4 - Viral Agents**

Arenaviruses (Togaviruses) - Group A Arboviruses

- Guanarito virus
- Lassa virus
- Junin virus
- Machupo virus
- Sabia virus

Bunyaviruses (Nairovirus)

- Crimean-Congo hemorrhagic fever virus

Filoviruses

- Ebola virus
- Marburg virus

Flaviruses (Togaviruses) - Group B Arboviruses

- Tick-borne encephalitis virus complex including Absetterov, Central European encephalitis, Hanzalova, Hypr, Kumlinge, Kyasanur Forest disease, Omsk hemorrhagic fever, and Russian spring-summer encephalitis viruses

Herpesviruses (alpha)

- Herpesvirus simiae (Herpes B or Monkey B virus)

Paramyxiviruses

- Equine morbillivirus

Hemorrhagic fever agents and viruses as yet undefined

## Toxins Table

Toxins with a mammalian $LD_{50}$ of < 100 mg/kg must be registered with the RM/EHOS. Therefore, use of the following toxins may require registration. If a toxin is not on the list, it still may require registration, depending upon the $LD_{50}$. For more information, please contact the RM/EHOS at 243-3995.

# Toxicity

$LD_{50}$ (mg/kg)*

Abrin 0.7
Aerolysin 7.0
Botulinin toxin A 0.0012
Botulinin toxin B 0.0012
Botulinin toxin C1 0.0011
Botulinin toxin C2 0.0012
Botulinin toxin D 0.0004
Botulinin toxin E 0.0011
Botulinin toxin F 0.0025
b-bungarotoxin 14.0
Caeruleotoxin 53

Cereolysin 40-80
Cholera toxin 250
*Clostridium difficile* enterotoxin A 0.5
*Clostridium difficile* cytotoxin B 220
*Clostridium perfringens* lecithinase 3
*Clostridium perfringens* kappa toxin 1500
*Clostridium perfringens* perfringolysin O 13-16
*Clostridium perfringens* enterotoxin 81
*Clostridium perfringens* beta toxin 400
*Clostridium perfringens* delta toxin 5
*Clostridium perfringens* epsilon toxin 0.1
Conotoxin 12-30
Crotoxin 82
Diphtheria toxin 0.1
Listeriolysin 3-12
Leucocidin 50
Modeccin 1-10
Nematocyst toxins 33-70
Notexin 25
Pertussis toxin 15
Pneumolysin 1.5
*Pseudomonas aeruginosa* toxin A 3
Ricin 2.7
Saxitoxin 8
Shiga toxin 0.250
*Shigella dysenteriae* neurotoxin 1.3
Streptolysin O 8
Staphylococcus enterotoxin B 25
Staphylococcus enterotoxin F 2-10
Streptolysin S 25
Taipoxin 2
Tetanus toxin 0.001
Tetrodotoxin 8
Viscumin 2.4-80
Volkensin 1.4
Yersinia pestis murine toxin 10

*Please note that the $LD_{50}$ values are from a number of sources (see below). For specifics on route of application (i.v., i.p., s.c.), animal used, and variations on the listed toxins, please go to the references listed below.

**Reference:**

1. Gill, D. Michael; 1982; Bacterial toxins: a table of lethal amounts; *Microbiological Review*s; 46: 86-94

2. Stirpe, F.; Luigi Barbieri; Maria Giulia Battelli, Marco Soria and Douglas A. Lappi; 1992; Ribosome-inactivating proteins from plants: present status and future prospects; *Biotechnology*; 10: 405-412

3. Registry of toxic effects of chemical substances (RTECS): comprehensive guide to the RTECS. 1997. Doris V. Sweet, ed., U.S. Dept of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health; Cincinnati, Ohio

## H. Intellectual Property Policy

### California State University, Dominguez Hills

### INTELLECTUAL PROPERTY POLICY: Version 1

## ARTICLE 1

**1.01 PURPOSE**

It has been the traditional practice of higher education in this country that books and other copyrightable materials created entirely through the individual initiative of an employee belong to the employee and that the employee has the right to copyright the material and to receive any subsequent royalties. On the other hand, where the employee either has been hired to create a specific product or has been assigned the duty to create a specific product, it has been the practice for colleges and universities to claim the copyright in the exclusive ownership of the final product. One purpose of this policy is to affirm these traditional practices.

Nevertheless, there are many possible variations between the two examples noted. These variations occur when an educational institution or system supports, in one form or another, employee research and creative effort. In such instances, the traditional practice of higher education fails to offer clear conclusions as to copyright ownership of the products produced, at least in part, through the support of the educational institutional system.

A second purpose of this policy is to provide a clear and equitable means to determine the respective rights of California State University, Dominguez Hills (CSUDH) and the employee in products supported by CSUDH.

A third purpose of this policy is to encourage, support, and reward scientific research and scholarship and to recognize the rights and interests of the inventor or creator, the public, the external sponsor, and the University.

California State University, Dominguez Hills is an academic, not commercial, institution that fosters the development and dissemination of knowledge, innovation, and intellectual productivity. Academic freedom of individuals takes precedence over potential monetary rewards. Therefore, this policy statement shall be implemented in keeping with: (a) the University's primary mission of teaching, research, and service, (b) those principles expressed in Sections 2.01 and 3.01.C below, and (c) other policy statements relating to sponsored research. The principles followed in this policy statement are independent of particular technologies. That is, the focus is on the intellectual process of creating the product, not on the nature of the product itself.

**1.02 GENERAL**

**A. Scope**. This policy addresses the rights to, and protection and transfer of, intellectual property created by University faculty, staff, or students. Issues not directly addressed in this policy, including disagreements concerning its application or interpretation, will be addressed and resolved consistent with applicable law or agreements and the principles and provisions of this policy.

**B. Governing Principles**. The following principles underlie this policy and should guide its application and interpretation:

1. **Academic Freedom and Preeminence of Scholarly Activities**. The missions of teaching and scholarship have preeminence over that of the transfer and commercialization of research results. The University's commitment to its educational mission is primary, and this policy does not diminish the right and obligation of faculty members to disseminate research results for scholarly purposes.

2. **Equity and Fair Play**. This policy applies to all faculty, staff, administrators, and students, whether or not particular research results are patentable, and regardless of the specific characteristics of a given discipline or the level of funding, facilities, and technical support available for the creative effort.

   This is not a detailed policy, and it has not been designed to address every conceivable circumstance. Under the Principle of Fair Play, the creators and the University mutually operate so

that no one will be allowed either to deliberately create or exploit inadvertent exceptions to this policy to his or her own advantage. If policy corrections or exceptions are nonetheless identified, appropriate recommendations shall be made to the President.

3. **Mutual Trust, Collegiality, and Goodwill**. Throughout all phases of the creation and in the implementation of this policy, it is assumed that all members of the University community will be guided by a sense of mutual trust, collegiality, and goodwill. In the event of future controversies regarding the rights to intellectual property, the commercialization of particular property, or in the interpretation of this policy, all parties should recognize that mutual trust, collegiality, and goodwill were fundamental tenets in the forging of this policy.

4. **Faculty Governance and Review**. University faculty, through the Faculty Policy Committee (FPC), shall play a preeminent role in the establishment and periodic revision of this policy and in the review and recommendation of dispute resolutions arising under it. The committee designated under this policy shall have a majority of voting members who are faculty without administrative appointments, and a faculty member shall chair the committee.

5. **Transparency**. The Principle of Transparency promotes both the disclosure and avoidance of actual and apparent conflicts of interest associated with external commercial activities by requiring that such activities be disclosed in advance. If the activities are consistent with this policy and its principles, the faculty, staff member, or student should have no reason not to disclose them. If the activity includes proposals for external research or project funding, the relevant CSUDH disclosure policy applies.

6. **Reasonableness in Licensing**. The inventor or creator shall normally play an active role in the entire licensing process, including consultation and/or approval of licensing decisions, particularly where the inventor or creator has no financial interest in the licensee. Otherwise, such participation shall be consistent with conflict of interest regulations or University policy.

# ARTICLE 2

## 2.01 OWNERSHIP AND OTHER INTERESTS

**A. Faculty and Student Ownership**. The results of scholarship and creative work are the property of the individuals who originate them and who, therefore, have the right to decide the final disposition of those results, e.g., copyright. However, the definition of these property rights must take into account the contributions by other persons, by institutions and by agencies. Intellectual property developed with substantial use of University financial support shall be the joint property of the developer and the University (or its auxiliary organization), unless such ownership is precluded by grant or contract agreements or by State or Federal law, or the University is the owner (as more fully explained below.). The University shall protect the rights of faculty and students to intellectual property and shall involve discoverers and creators in the process to determine how such intellectual property shall be made public. Any income generated by the intellectual property shall be distributed in accordance with Article 5.

1. **Basis of University Interest**. The University's interest in faculty or student intellectual property shall be limited to those cases in which the property was created as the result of the substantial use of financial support or other University resources in the development of that intellectual property and such intention of the University to solely or jointly own the property is either customary or explicitly bargained for, in writing, by the University and the employee, independent contractor or student. In keeping with traditional academic policy, the University does not assert ownership of copyrightable material due to provision of office space, computers or like equipment, or library facilities, unless the resources are provided specifically to support the development of the material. The University does not claim ownership of books, articles, course materials, and similar works that disseminate research and scholarly results or from preparation for classroom teaching, nor does the University claim ownership of popular nonfiction, fiction, poetry, musical compositions or other works of artistic imagination, which are not institutional works. Nor does a faculty member's general obligation to produce scholarly works constitute a basis for University interest.

The normal and routine use of University personnel, resources, or facilities consistent with one's assigned duties and responsibilities does not constitute "substantial use (including property created, modified, updated, etc. created during the school year or while on assigned time, sabbatical, difference in pay leave, and similar University support unless specifically agreed to in advance.).

Substantial use of financial support and University resources are evidenced as follows:

**a. Substantial Financial Support**. Substantial financial support is evidenced by the acceptance by the faculty member or student of CSUDH financial support specifically initiating the development of intellectual property. For example, acceptance of a grant, contract, stipend, or of academic release time developed by the University specifically for its stated and specific purposes (which is then carried out by the faculty member or student) and leads directly to the development of intellectual property constitute substantial financial support. General (open to all or a subgroup of faculty or students) University research awards and leaves do not constitute such support.

In cases where copyright or patented materials are the major responsibility of the University employee, then the presumption shall be that the University shall own the property rights. For example, if the individual is hired, as an employee, student, or independent contractor specifically to create custom software (such as for registration or alumni relations) that software and all rights thereto shall belong to the University, unless there is an explicit agreement granting rights to the employee, student, or independent contractor.

**b. University Resources**. Substantial use of University resources is evidenced by the use of those resources outside the context of normal academic duties that directly contribute to the development of intellectual property(s); for example, the use of University laboratories which contribute directly to the development of the intellectual property. The use of the library, faculty offices, campus computers or related equipment, CSU Research and Creative Activity awards, faculty development awards, and sabbatical and differential pay leaves, however, do not constitute the substantial use of University resources.

In the case where copyrightable material is prepared because the University supplies extra or special support directly for that purpose and there is additional resource cost to the institution, the product is considered substantially supported by the institution. "Extra" or special institutional support includes those support costs, which would not have been incurred by the institution in the absence of the development of the product. For example, concurrent use of University facilities does not, in general, generate additional out-of-pocket costs to the University. If extra or special University support is provided, the University will specify that extra or special support in writing and will normally retain copyright.

**B. Staff and Works-for-Hire**. The University may employ or engage individuals under terms that include the specific determination or allocation of intellectual property rights between the parties. Open and full disclosure in advance of such creative activity, or as soon thereafter as is practicable, is a prerequisite to a fair determination or allocation of ownership to staff creations or inventions. Inventions or creations by staff (non-faculty) directly incident to their employment or engagement—such as a specific job requirement or assigned duty—belong to the University. The University shall have an equity interest in works and inventions by staff employees, not incident to their employment, where substantial University resources have been used in the development of the work or invention (refer to Article 2.A.1. "Basis of University Interest").

Staff creations or inventions not involving significant University resources (including the creator/inventor work-time) are owned exclusively by the creator/inventor.

**C. Externally Sponsored Work**. Intellectual property conducted under the auspices of an external sponsor and the university (CSUDH or CSU) shall be owned as specified in said agreement. It is the responsibility of the Office of the Dean of Graduate Studies and Research to inform each person whose intellectual rights are limited by an externally sponsored contract of the intellectual property provisions of that contract

contract in advance of the beginning of work thereon. Such notice is to be in writing and the University may require written acknowledgment of such provisions by any person working on externally sponsored projects. A summary of external sponsorship agreements made by either CSUDH or the CSU shall be maintained by the Office of the Dean of Graduate Studies and Research and shall be available to the general university community.

If the university fails to notify a creator, effectively and in advance, of limitations imposed on his or her intellectual property rights by external sponsorship agreements, the creator is entitled to receive from the university 50% (fifty percent) of the net proceeds to CSUDH or the CSU resulting from his or her intellectual property.

# ARTICLE 3

## 3.01 ADMINISTRATIVE PROCEDURES

**A. University Administration**. The University President is responsible for policy matters relating to intellectual property and affecting the University's relations with inventors and creators, public agencies, private research sponsors, industry, and the public. The Office of Vice President for Academic Affairs, through the Dean of Graduate Studies and Research, and in coordination with the CSUDH Foundation, shall implement and administer this policy, including administrative decisions regarding the evaluation of patentability or other forms of intellectual property protection, filing for patents, use rights, and the pursuit of infringement actions.

**B. Intellectual Property Review**: The Faculty Policy Committee (FPC) of the Academic Senate shall be charged with reviewing this policy and any other issues raised concerning intellectual property. FPC shall be consulted in advance concerning any material changes to the policy. There shall also be an Intellectual Property Administrative Procedures Committee (IPAPC). A member of FPC will chair the committee. . This Committee consists of the Dean of Graduate Studies and Research, a student representative appointed annually by Associated Students, Inc., the Vice President for Academic Affairs, Vice President for Administration and the Director of Research and Funded Projects. The CSUDH Executive Director of the Foundation shall be a non-voting ex officio member of the Committee. The IPAPC shall review and monitor University activities on matters relating to the administration of this policy. and shall advise the President on policy matters related to the distribution of Intellectual Property Development and Intellectual Property research funds.

**C.** At the beginning of each academic year, the CSUDH Foundation will provide to the Dean of Graduate Studies and Research a summary statement of income and expenses from intellectual property in which the University has an interest. The Dean will submit this information to the committee that oversees Intellectual Property in a written report of all the relevant activities in which that office has been involved in the preceding year.

**D. Disclosures**. In order to preserve the rights of all concerned, a CSUDH employee shall disclose to the University the existence of patentable discoveries or inventions made by him/her while under hire or contract with the University. This should be accomplished as quickly as possible so that the University might act to preserve the rights of employees. Patentable discoveries or inventions conceived or reduced to practice by the University faculty, staff or students using University resources or resources administered by the University or within the inventor's or creator's scope of employment, shall be disclosed in writing using a signed and dated "disclosure form: submitted to the Dean of Graduate Studies and Research. The Dean of Graduate Studies and Research will refer the disclosure to the Intellectual Property Rights Administrative Procedures Committee for a recommendation as to the rights assigned to parties. To the degree possible within this practice, disclosure statements shall be kept in confidence. The guiding principle in the determination of ownership and rights shall be the circumstances of its creation, not the nature of the product itself and the presumption is that the creator reserves all rights to patentable discoveries or inventions.

As part of disclosure preparatory to filing a patent application, where that is appropriate, discovers and

inventors should be prepared to provide suitable notebook entries, sketches, descriptions, and other evidence of development of the concepts through successive stages.

**E. Use Rights.** Inventors or creators having identified a potential licensee may request that the potential licensee be given the right of first negotiation, consistent with University policy on conflicts of interest or other applicable University policies.

**F. Confidentiality**. It is customary and prudent for those involved within the University and external to the University to enter into appropriate confidentiality agreements if they have access to any proprietary information on specific patentable discoveries or inventions (i.e., Disclosure Statement and other supporting information). The Dean of Graduate Studies and Research will be responsible for securing and maintaining such agreements in the chain of use-rights processing.

**G. Assignments of Interest**. All transfers of ownership between those with any interest in patentable discoveries or inventions shall be documented through appropriate legal instruments, such as assignment agreements, in a form consistent with applicable law and regulations.

## ARTICLE 4

### 4.01 Production and Use Involving Non-University Agencies or Involving Other Education Institutions or Systems

The University may administer funds provided by non-University agencies (such as the Federal Government, corporations, or foundations) or in conjunction with other government entities or a consortium thereof under contract or grant to pay for staff time, services, or material incident to the creation or reduction to practice of intellectual property. In such cases, the University may enter into agreements with such agencies recognizing their rights, in whole or in part, to the ownership of the intellectual property produced from its use and to the net income from its use, and to reasonable participation in determining the conditions of use. The University President or designee will inform members receiving payments from funds provided by non-University agencies as to the rights reserved to such agencies under the agreement between those agencies and the University.

## ARTICLE 5

### 5.01 INCOME ALLOCATIONS

**A. General Objectives**. In the transfer of intellectual property and allocation of funds derived from income-producing intellectual property, the general objectives are to assure the transfer and development of those discoveries for the public benefit, direct funds toward the inventors or creators, and, where appropriate, provide for the funding of future creative effort by University faculty, students, and staff.

It shall be the policy of the University that intellectual property pursuant to this policy shall, in those cases specified by 2.01.A.1.b be available for use without fee of any kind for any educational or non-commercial purpose by any campus or any entity of the California State University.

**B. Allocation of Income from Intellectual Property**. Net income will be allocated to the inventors or creators and the University. Annually, or upon request, the CSUDH Foundation will provide an inventor or creator with a current expense statement relating to his or her specific intellectual property.

**1.** Income derived from property produced outside the conditions specified in 2.01.A.1.b shall belong to the creators or inventors.

**2.** The President of CSUDH in consultation with the Committee that reviews intellectual property issues will determine the distribution of net income derived from intellectual property owned by the University.

**3.** In the case of intellectual property being developed by an employee who has been commissioned by the University to create the product, the University will own the copyright and the final product and will be entitled to 100 percent of all royalties derived from the intellectual property.

4. The University shall have no vested interest in inventions clearly resulting from personal or private research and developed by a person on her or his own time, without cost or expense to the University. The faculty member may voluntarily offer such invention to the University for the possible securing of a patent and for subsequent developing, processing, and exploitation under University aegis. If the University accepts such an offer, the terms of the agreement shall be determined jointly by the faculty member and the University.

## ARTICLE 6

### 6.01 CSUDH FOUNDATION

The CSUDH Foundation is a non-profit, public benefit corporation serving as a qualified auxiliary organization in support of the University. The CSUDH Foundation functions in several roles relating to the perfection, protection, transfer, and development of intellectual property discovered or having interests therein held by the faculty, students, campus staff, or the University.

**A. Perfection**. The perfection of legal and equitable rights in intellectual property generally involves rather exacting documentation and compliance with statutory and regulatory procedures. The CSUDH Foundation typically acts as the contracting agency for externally sponsored research projects on behalf of the University and the principal investigator. Sponsored research agreements may have specific conflict of interest requirements, invention or creation disclosure requirements, and/or patent/copyright and licensing provisions requiring compliance through the CSUDH Foundation.

The CSUDH Foundation, in cooperation with the Dean of Graduate Studies and Research, will develop and document a standardized confidential invention disclosure and reporting process for the protection of the rights and interests of the inventor or creator, consistent with this policy statement and sponsored project requirements.

**B. Protection**. At the request of the Dean of Graduate Studies and Research, or in satisfaction of sponsored research requirements, the CSUDH Foundation shall initiate action to further evaluate the need for and practicality of securing appropriate statutory protection over any intellectual property subject to this policy. Results of any such evaluations shall be reported to the Dean of Graduate Studies and Research and the inventor or creator.

**C. Transfer and Development**. The CSUDH Foundation often serves as the transfer and development agent for those with legal and/or equitable rights to intellectual property subject to this policy statement. Actions to evaluate protection typically also involve the assessment of commercial viability, and may, in most circumstances, require the CSUDH Foundation to negotiate among the interested parties appropriate assignment and collateral agreements to settle those interests and obligations, and to assure property protection and development opportunities.

**D. Fiscal Agent**. The CSUDH Foundation also serves as the designated fiscal agent of the University in the administration of transactions involving University interests in such intellectual property, and may also serve in a similar capacity for other interest holders at their request.

**E. CSUDH Foundation Services**. In providing the above services, the CSUDH Foundation may be entitled to recover its costs in accord with established University and CSUDH Foundation cost recovery policy.

## ARTICLE 7

### 7.01 IMPLEMENTATION PRACTICES

The Dean of Graduate Studies and Research, in cooperation with the CSUDH Foundation's Executive Director, shall develop and document, implement, and maintain on a current basis appropriate procedures and practices to carry out this policy statement. The Intellectual Property Review Committee shall be consulted on any significant proposed practices involving the application or interpretation of this policy.

# ARTICLE 8

## 8.01 PERIODIC POLICY REVIEW

The Intellectual Property Review Committee shall review this policy as needed and at least every four years to make recommendations for any changes.

### Glossary of Key Terms

Definitions of key terms used in this policy are given below.

1. **"Disclosure Statement"** means a confidential, written record of an invention or creation by the invention creator used to help assess the nature, extent, and likely intellectual property interests in and development potential of the invention/creation.

2. **"Literary and Artistic Works"** mean original works of authorship fixed in tangible media of expression.

   The following definitions are, for the most part, taken from pertinent federal statutes:

3. **"Intellectual property"** Although the law provides for several different types of Intellectual Property, faculty concerns center on two: copyrights and patents.

   **a.** "Copyright" shall be understood to mean that bundle of rights that protect original works of authorship fixed in any tangible medium of expression, now known or later developed, from which they can be perceived, reproduced, or otherwise communicated, either directly or with the aid of a machine or device.

   **b.** "Patent" shall be understood to mean that bundle of rights that protect inventions or discoveries which constitute any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof; new and ornamental designs for any useful article and plant patents being for the asexual reproduction of a distinct variety of plant, including cultivated sprouts, mutants, hybrids, and new found seedlings, other than a tuber propagated plant or plant found in an uncultivated state.

4. **"Works of Authorship"** (including computer programs ) programs) comprise, but are not limited to the following: literary works, musical works, including any accompanying words; dramatic works, including any accompanying music; pantomimes and choreographic works; pictorial, graphic, and sculptural works (photographs, prints, diagrams, models, and technical drawings) motion pictures and other audiovisual works; sound recordings; and architectural works.

   [Note on computer software: Computer programs fall into a gray area between the two types of intellectual property. Programs that are a part of a "new and useful process" may be eligible for patent protection, while programs embodying minimally original expression may be eligible for copyright protection.]

5. **"Scholarly Works"** mean books, articles, and other literary and artistic works developed without commercial objectives for the primary purpose of disseminating knowledge or beauty.

6. **"Income and Net Income"** The term "income" means royalties and related or similar funds received from the transfer or licensing of intellectual property. "Net income" means the balance of income remaining after direct expenses related to generating and securing income from specific intellectual property and any direct costs or special advances of the University or CSUDH Foundation. Such direct costs typically include legal filing fees, patent applications, issuance and maintenance charges, transfer or licensing costs, travel, and product development costs. General administrative costs or special advances and repayment terms shall be identified and detailed in writing at the time they are made.

7. The terms **"Inventions," "Discoveries," or "Other Inventions"** include tangible or intangible inventions, whether or not reduced to practice, and tangible research results whether or not patentable or

copyrightable. Such research results include, for example, computer programs, integrated circuit designs, industrial designs, databases, technical drawings, biogenic materials, and other technical creations.

8. **"University"** means California State University, Dominguez Hills, and includes the Extended Education Division.

9. **"Product"** includes, but is not limited to, writings, musical or dramatic compositions, sound recordings, films, lecture notes, videotapes and other pictorial reproductions, computer programs, listings, flow charts, manuals, codes, instructions, software, web pages, multimedia presentations and products, (e.g. CD-ROMs) and other copyrightable works.

10. **"Property Development and Intellectual Property Research Revenue"** includes, but is not limited to, income received by the University as a result of writings, musical or dramatic compositions, sound recordings, films, lecture notes, videotapes and other pictorial reproductions, computer programs, listings, flow charts, manuals, codes, instructions, software, and other copyrightable works.

11. **"Works for Hire"** refers to intellectual property developed under terms that include the specific determination or allocation of intellectual property rights between the parties.

12. **"Externally Sponsored Work"** refers to intellectual property created as a result of work conducted under an agreement between an external sponsor and the University or The California State Universities that specifies the ownership of such intellectual property.

**CSUDH gratefully acknowledges the CSU Bakersfield Intellectual Property Policy as the basic model for the CSUDH policy as well as the American Association of University Professors (AAUP), University of California, Carnegie Mellon University, and the authors Gorman (1998), Scott (1998), and Thompson (1999) for delineating salient issues and principles.**

**PM 01-04**

# I. Non-Resident Alien Tax Compliance Issues

**Non-Resident Alien Tax Compliance Issues**

California State University, Dominguez Hills
Business Process Management Department

General Information

Federal Internal Revenue Service (IRS) regulations have been established for individuals and companies from foreign countries who receive any form of payment made with United States money. Payments made to employees and special consultants, as well as payments made for honoria, travel expenses, scholarships, contracts and others are included in these regulations and may be taxable. The California State University Office of the Chancellor has given a directive to all actively implement compliance of these regulations.

The United States has tax treaties with many countries throughout the world. The IRB Regulations related to identification of Non-Resident Aliens (NRA) for tax persons is somewhat complex. An analysis must be made on a case by case basis using hiring or payment documents to determine the USA tax requirements, i.e. the country of residency must be determined, type of visa a person holds, when the person entered the country and so on. Until the analysis is completed, the University (including the Foundation) will not know whether or not a payment will be taxable. David McCulloch, Non-Resident Alien Tax Compliance Coordinator, is performing the analysis using hiring or other payment documents.

The IRS does not distinguish the source of a payment made on campus. This requires the campus to coordinate and gather information on an on-going basis for State funded payments and CSUDH Foundation payments. Annually, the campus and auxiliaries are required to report to the IRS all payments made to identified taxable NRAs. Non-compliance for not collecting the taxes has resulted in substantial IRS fines for many colleges and universities across the country.

Through communication, cooperation and coordination, CSUDH will be able to meet compliance with IRS regulations. The Department of Business Process management within the Division of Administration and Finance has been identified as the coordinating entity for the campus (including CSUDH Foundation). It is working with other campus units, i.e. Human Resources Management, Foundation, etc. to identify possible NRAs. The department is providing the guidance and performing all assessments related to the NRA IRS tax regulations.

If you have questions regarding non-resident alien tax issues, please do not hesitate to contact **David McCulloch, Non-Resident Alien Tax Compliance Coordinator at (310) 243-2849.**

## J. Full Cost Reimbursement/Waiver Request Form

### Faculty/Employee Full Cost Reimbursement/Waiver Request Form

It is the policy of California State University, Dominguez Hills to request from all granting entities a full reimbursement of salary and benefits for faculty and other employees engaged in grant or contract activities. This policy conforms to California State University directives outlined in BA 83-30 and E.O. 753.

It is recognized, however, that there may be extraordinary circumstances that may not permit a full reimbursement. If such circumstances exist, the university must make a determination to request the grant or contract based upon its substantial and significant benefit to the mission of the institution. Below (or attached) please provide justification for an exception to the requirement of requesting and/or obtaining full reimbursement of salary and benefit costs for a faculty member or other employee being released to work on a grant or contract. If appropriate, also indicate if other funding has been identified to off-set the salary and benefits costs. A waiver request must also be submitted if funding negotiations are entered into with the granting agency, after the grant or contract is submitted, and there is a probability that full reimbursement will not be received.

Project Title: _____

Salary Reimbursement Requested: _____ Benefits Reimbursement Requested: _____

*Grant project MUST directly benefit the mission of the university. Please state benefit to the institutional mission in justification.*

_____ Granting agency will not fund full reimbursement costs OR

_____ Other (please be specific in justification)

Justification:

_____ _____

Project Director's Signature Date Dean's Approval Signature Date

_____

Provost's (or designee) Approval Signature Date

Note: For initial grant submissions, attach this form to the (grant) CSUDH Proposal Approval Form 9/2007