



Joint Legislative Audit Committee

Office of the Auditor General



REPORT TO THE CALIFORNIA LEGISLATURE



AN OPERATIONAL REVIEW OF THE SOLANO INSTITUTE FOR MEDICAL AND PHARMACOLOGICAL RESEARCH

Office of the Auditor General

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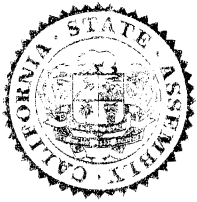
REPORT OF THE
OFFICE OF THE AUDITOR GENERAL
TO THE
JOINT LEGISLATIVE AUDIT COMMITTEE

712

AN OPERATIONAL REVIEW OF
THE SOLANO INSTITUTE FOR
MEDICAL AND PHARMACOLOGICAL RESEARCH

DEPARTMENT OF CORRECTIONS

NOVEMBER 1977



Joint Legislative Audit Committee

OFFICE OF THE AUDITOR GENERAL

California Legislature



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November 7, 1977

The Honorable Speaker of the Assembly
The Honorable President pro Tempore of the Senate
The Honorable Members of the Senate and the
Assembly of the Legislature of California

Members of the Legislature:

Your Joint Legislative Audit Committee respectfully submits the Auditor General's operational review of the Solano Institute for Medical and Pharmacological Research.

Since 1967 the Institute, a nonprofit California corporation under contract with the California Department of Corrections, has been administered by a citizen Board of Directors independent of the Board of Corrections. During the past four years, research projects utilizing prison inmates have been undertaken in the areas of skin sensitivity, drug safety, drug tolerance and drug efficacy.

By copy of this letter, the Department is requested to advise the Joint Legislative Audit Committee within sixty days of the status of implementation of the recommendations of the Auditor General that are within the statutory authority of the Department.

The auditors are Harold L. Turner, Audit Manager; Charles A. Dobson, CPA; Edwin H. Shepherd; and J. Peter Bouvier.

Respectfully submitted,

MIKE CULLEN
Chairman

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SUMMARY

The Solano Institute for Medical and Pharmacological Research (SIMPR) sponsors and conducts basic and applied medical and pharmacological research. Prison inmates, on a voluntary basis, serve as the subject group for these research studies. Our examination included a review of the operations and financial activities of SIMPR for the years 1973 to 1976. We found that:

- Inmates who are employed by SIMPR in pay-work positions receive a disproportionate share of the available research monies at the California Medical Facility (CMF) at Vacaville. We recommend that SIMPR's Board establish procedures to ensure that all qualified inmates have an equal opportunity to participate in research projects at CMF (see page 8).
- As a result of system control deficiencies in the SIMPR research approval process, the potential exists for multiple interests to develop among SIMPR Board members when they are involved in both the approval and conduct of research projects. We recommend that the contract between the State of California and SIMPR be amended to eliminate this potential problem (see page 11).

INTRODUCTION

We have examined the operations and financial activities of the Solano Institute for Medical and Pharmacological Research (SIMPR) for the calendar years 1973 to 1976. Our examination was made pursuant to a resolution of the Joint Legislative Audit Committee and under the authority vested in the Auditor General by Section 10527 of the Government Code.

We did not perform a full financial audit of SIMPR or its financial statements and therefore we do not express an opinion on them. This disclaimer of opinion is required by Rule 58.2 of the California Accountancy Act when the name of certified public accountants is associated with unaudited financial statements, or portions thereof, such as those attached to this report.

SIMPR (a nonprofit California corporation) was established in 1962 to encourage, sponsor and conduct basic and applied medical and psychiatric research. Currently SIMPR has a five-year agreement ending on May 31, 1981 with the State of California, Department of Corrections, California Medical Facility (CMF), Vacaville. This agreement allows SIMPR to sponsor and conduct basic and applied medical and pharmacological research with prison inmates; assemble, correlate, evaluate, compile and disseminate data, findings and conclusions; make recommendations; and encourage communication among individuals and organizations interested in its purposes.

SIMPR is currently governed by a Board of Directors who are drawn from the community at large and are independent of the California Department of Corrections (CDC). If a research proposal meets standards of safety and inmates freely volunteer, CDC permits inmate participation in SIMPR-sponsored research.

The research program at CMF is intended to provide an opportunity for inmate volunteers to engage in socially useful acts and at the same time receive financial benefits from the participation. The public benefits also from the advances in medical knowledge.

A research project conducted at CMF must be reviewed and approved by the following:

- A University of California Human Experimentation Review Committee or five outside consultants for researchers not affiliated with the University
- The Research Review Committee of SIMPR
- The California Medical Facility Institutional Research Review Committee
- The California Department of Corrections.

Future research projects must also be approved by the newly created Institutional Review Board.*

* The Institutional Review Board was created by Chapter 1250 of the California Statutes of 1977.

During calendar years 1973 to 1976, CDC approved 37 SIMPR research projects to be conducted at CMF. These projects may be grouped into the following categories:

- Skin Sensitivity--a small amount of a test preparation applied under a bandage to determine if the skin reacts to the chemical
- Drug Safety--a single dose administered to a volunteer to determine the safety and pharmacological activity of the drug
- Drug Tolerance--multiple doses administered to determine the safety and pharmacological activity and the possible effects of the drug upon the body as monitored by clinical, biochemical and hematological tests
- Efficacy--drugs administered to test the power of a drug to produce an intended result.

AUDIT RESULTS

SIMPR-EMPLOYED INMATES
RECEIVE A DISPROPORTIONATE
SHARE OF RESEARCH COMPENSATION

During the last six months of 1976, inmates who worked for SIMPR as clerks or laboratory technicians participated more frequently in research projects and received greater total compensation than other inmates who did not work for SIMPR and volunteered to participate. The SIMPR-employed inmates received an average of \$90.80 per month for research participation. In one month, several inmates received compensation in excess of \$200. Inmates not otherwise affiliated with SIMPR averaged only \$25.26 per month for research participation. An average of 368 inmates per month were involved in research during the period. An average of 20 of these inmates were also employed by SIMPR.

One factor contributing to this differential in pay is that SIMPR-employed inmates work on a day-to-day basis in the research area of the facility. This adds an element of convenience to their selection for studies. On the other hand, these inmates have also proven their reliability through prior research studies, which, in part, accounts for the increased frequency with which they are selected to participate.

CMF's policy requiring inmates to participate in three skin sensitivity studies before they can become eligible for internal medication studies may also contribute to the disparity in inmate pay. The compensation for skin sensitivity studies is much lower than that received for participation in internal medication studies. This policy was established to evaluate the dependability of each volunteer as a research subject.

The strict medical criteria for inmate selection is another factor which reduces the number of inmates who participate in internal medication studies. An inmate may not be selected for these studies if a physical examination or review of his medical history reveals any abnormalities, or if he is currently on institutionally prescribed medication.

Table 1 compares SIMPR-employed inmate research compensation with non-SIMPR-employed inmate research pay. The majority of the SIMPR-employed inmates worked as both clerks and laboratory technicians and were also compensated for these duties.

Recently enacted legislation requires that the procedures for selecting inmates be equitable and that inmates not be unjustly deprived of the opportunity to participate. If properly implemented, this legislation should reduce the disparity of compensation between SIMPR-employed and non-SIMPR-employed inmates.

TABLE 1
 INMATE RESEARCH COMPENSATION
 SIMPR-EMPLOYED vs. NON-SIMPR-EMPLOYED
 JULY 1976 TO DECEMBER 1976

SIMPR-Employed Inmates	Monthly Research Compensation						
	July	August	September	October	November	December	Total
A	\$ 120.05	\$ 97.50	\$ 12.50	\$ 80.00	\$ 26.00	\$ 192.50	\$ 528.55
B	121.30	87.50	*	50.00	26.00	192.50	477.30
C	65.00	125.00	57.00	65.00	87.00	162.50	561.50
D	117.30	107.50	57.00	95.00	62.00	167.50	606.30
E	65.00	37.50	34.50	167.75	87.00	42.50	494.25
F	*	*	*	*	42.00	200.50	242.50
G	22.50	122.50	34.50	55.00	52.00	162.50	449.00
H	145.00	92.50	57.00	97.00	94.00	192.50	678.00
I	113.85	92.50	87.00	65.00	72.00	197.50	627.85
J	50.00	95.00	63.50	87.00	72.50	192.50	560.50
K	*	30.00	34.50	52.50	17.00	212.50	346.50
L	117.30	152.50	88.50	114.50	116.00	195.00	783.80
M	61.55	100.00	109.00	97.00	109.00	165.00	641.55
N	65.00	60.00	109.00	87.00	94.00	192.50	607.50
O	55.00	125.00	54.50	65.00	64.00	195.00	558.50
P	25.00	88.35	69.50	32.50	52.00	172.50	439.85
Q	97.00	85.25	74.50	*	15.00	30.00	301.75
R	105.35	87.50	69.50	65.00	37.00	197.50	561.85
S	39.05	82.50	69.50	72.50	22.00	222.50	508.05
T	*	*	*	*	37.00	*	37.00
U	72.30	150.00	79.50	75.00	124.50	*	501.30
V	6.00	20.00	*	*	*	*	26.00
W	*	50.00	34.50	*	*	*	84.50
Total Compensation	<u>\$1,463.55</u>	<u>\$1,888.60</u>	<u>\$1,255.50</u>	<u>\$1,422.75</u>	<u>\$1,308.00</u>	<u>\$3,285.50</u>	<u>\$10,623.90</u>
Number of Participants	<u>19</u>	<u>21</u>	<u>19</u>	<u>18</u>	<u>21</u>	<u>19</u>	<u>19.5**</u>
Average Monthly Compensation	<u>\$ 77.03</u>	<u>\$ 89.93</u>	<u>\$ 66.08</u>	<u>\$ 79.04</u>	<u>\$ 62.29</u>	<u>\$ 172.92</u>	<u>\$ 90.87**</u>
<u>Non-SIMPR-Employed inmates</u>							
Total Compensation	<u>\$7,856.10</u>	<u>\$6,280.00</u>	<u>\$6,165.90</u>	<u>\$10,602.60</u>	<u>\$4,780.35</u>	<u>\$17,063.00</u>	<u>\$ 8,791.59**</u>
Number of Participants	<u>389</u>	<u>241</u>	<u>312</u>	<u>346</u>	<u>261</u>	<u>539</u>	<u>348**</u>
Average Monthly Compensation	<u>\$ 20.20</u>	<u>\$ 26.06</u>	<u>\$ 19.76</u>	<u>\$ 30.64</u>	<u>\$ 18.32</u>	<u>\$ 31.66</u>	<u>\$ 25.25**</u>

*Inmate did not participate in research.
 **Average for the six months.

CONCLUSION

The selection policies used by SIMPR do not allow all inmates an equal opportunity to participate in research. As a result, inmates who work for SIMPR as clerks or laboratory technicians receive a disproportionate share of the research compensation.

RECOMMENDATION

We recommend that:

- Because of the large differential in inmate pay between skin sensitivity and internal medication studies, potential participants should be categorized into two groups based upon eligibility for the types of studies. Any qualified inmate may participate in both types of research. When research studies develop, inmates should be selected equitably on a rotational basis.
- SIMPR should prepare and submit periodic reports to CDC to ensure that all qualified inmates have an equal opportunity to participate in research.

BENEFIT

Implementing these recommendations would allow qualified inmates an equal opportunity to participate in both high and low income-producing research studies and thereby spread the financial benefits of research more equally among the inmate population of CMF.

SIMPR'S-OPERATING PROCEDURES
DO NOT PRECLUDE BOARD MEMBERS
FROM HAVING MULTIPLE INTERESTS
IN RESEARCH PROGRAMS

There are no controls built into the research project approval system which preclude one individual from occupying several key positions in the research approval process. Each level in the approval process should function as a control over that process and the previous review levels to ensure that the research objectives are being met.

The following examples are not intended to indicate that apparent improper practices have occurred in SIMPR's past, but rather to demonstrate that the potential for multiple interest exists and may have a detrimental impact on the research program conducted through SIMPR at the California Medical Facility (CMF), Vacaville.

Example 1

The first Chairman of SIMPR's Board of Directors was also the Superintendent of CMF. SIMPR's Board approved a research project entitled X-75 which was to be conducted by the Chairman/Superintendent as the principal researcher, after his resignation or retirement as Superintendent of CMF.

The funds to support project X-75 were provided from SIMPR's net operating income. The total proposed cost of the project was \$200,000, of which \$100,000 was to be paid to the Chairman/Superintendent as a salary for performing the project.

The Director of CDC, upon discovering the project, disapproved project X-75 and directed that department employees presently serving on the SIMPR Board resign. Prior to the Chairman/Superintendent's resignation as chairman in 1967, the SIMPR Board donated the funds set aside for project X-75, in the amount of \$69,772.45, to a charitable organization.

The 1973 CMF policy statement requires SIMPR's Board members to be independent of CDC.

Example 2

The second Chairman of SIMPR's Board of Directors also functioned in the capacity of principal researcher. In addition he was instrumental in developing numerous research projects which were conducted at CMF. Excess funds remaining at the conclusion of his projects were frequently donated by SIMPR's Board to the Regents of the University of California. During the four-year period 1973 through 1976, SIMPR donated approximately \$78,000 to the University.

SIMPR's Chairman was also the chairman of a medical department within the University. SIMPR donated the funds to the University under the provision that they be restricted to the Chairman's discretionary use. A review of the expenditures of these funds indicated that they were used to support the operations of his department at the University.

The Chairman died in 1976. As of December 31, 1976, SIMPR's financial records indicated that the Chairman had approximately \$74,500 in advance research payments to SIMPR. At the September 23, 1977 SIMPR Board of Directors' meeting, the Board unanimously voted to donate \$32,000 to the Chairman's memorial fund, to be used in the college of medicine at the University. It was further agreed that this payment would release SIMPR of all "total and future obligations" to the Chairman's estate.

In this case, one individual was involved in developing, approving and conducting research at CMF, as well as approving and controlling the disposition of funds donated to the University.

CONCLUSION

As a result of system control deficiencies in the SIMPR research program conducted at CMF, the potential exists for multiple interests to occur when Board members are included in both the approval and conduct of research projects. This may not be in the best interest of the research effort.

RECOMMENDATION

The contract between the State of California and SIMPR should be amended to preclude members of SIMPR's Board of Directors from serving in any other capacity dealing with either the conduct of the research or the research approval process.

BENEFIT

Implementing this recommendation would add to the integrity of SIMPR's research efforts through increased assurances that multiple interest will not occur.

OTHER INFORMATION
REQUESTED BY THE LEGISLATURE

Profitability of SIMPR

SIMPR's income exceeded expenses by \$40,606 for the four years ending December 31, 1976. A summary of SIMPR's unaudited revenues and expenses is presented below.

SUMMARY OF REVENUES AND EXPENDITURES
(Unaudited)

	<u>1976</u>	<u>1975</u>	<u>1974</u>	<u>1973</u>
Gross Revenue	\$293,186	\$537,258	\$374,865	\$336,455
Expenditures	<u>303,245</u>	<u>496,868</u>	<u>351,982</u>	<u>349,063</u>
Income or (Loss)	<u>\$(10,059)</u>	<u>\$ 40,390</u>	<u>\$ 22,883</u>	<u>\$(12,608)</u>

A detailed statement of revenue and expenses is presented in Appendix A.

Sources of SIMPR's Revenue

Over 98 percent of SIMPR's revenue was received from four doctors who conducted research at CMF. Three of the principal researchers were affiliated with the University of California and the fourth was performing independent research. One of the doctors was also the Chairman of SIMPR's Board of Directors.

Sources of Principal
Researchers Funds

Of the 37 projects approved during 1973 through 1976, 36 were sponsored by pharmaceutical companies and one was sponsored by the U. S. Department of Health, Education and Welfare (DHEW). In addition, two of the principal researchers conducted ongoing skin sensitivity studies. Those studies were sponsored by cosmetic companies, drug companies, DHEW, the Food and Drug Administration and the State of California.

A partial listing of companies which supported research through SIMPR is presented below.

Merck and Company	Beecham-Massingil
Wyeth Laboratories	Merril National Labs
McNeil Laboratories	Warner Lambert
Vick Chemical Company	Hoffmann LaRoche, Inc.
Miles Laboratories	Upjohn Company

Consulting Fees Received
by Principal Researchers

Principal researchers are normally contacted directly by pharmaceutical company representatives and are requested to perform specific research projects. Because this is proprietary information, it is impossible to determine the exact amount of compensation received by the principal researchers.

SIMPR's records did disclose that one of the principal researchers received \$20,975 over a four-year period for consulting services. Another researcher estimated that he annually received \$10,000 or \$15,000 for the projects he performed at CMF. One researcher would not provide any information regarding his funding sources nor the amount he received in fees for the research he performed. Between 1973 and 1976 SIMPR paid a total of approximately \$160,000 in consulting fees.

Inmate Wages

SIMPR pays inmates for participation in research projects and provides monthly salaries to a limited number of inmates who perform certain clerical and technical duties. The majority of the payments were for research participation, with relatively minor amounts paid to inmate clerks and lab technicians. Based upon the total amount paid to inmates, SIMPR contributes an additional 10 percent to the Inmate Welfare Fund. One-half of the amount paid to the Inmate Welfare Fund is used to establish inmate pay-work positions outside the research field at CMF. Over the four-year period 1973 to 1976 inmates received \$757,390, which represents 50.5 percent of the total cost incurred by SIMPR. A breakdown of payments to inmates is presented below.

SUMMARY OF INMATE COMPENSATION
(Unaudited)

	<u>Research</u>	<u>Pay-Work</u>	<u>Inmate Welfare Fund</u>	<u>Total</u>
1973	\$155,559	\$ 2,167	\$15,772	\$173,498
1974	164,597	2,164	16,676	183,437
1975	232,674	2,758	23,542	258,974
1976	<u>125,708</u>	<u>2,911</u>	<u>12,862</u>	<u>141,481</u>
Total	<u>\$678,538</u>	<u>\$10,000</u>	<u>\$68,852</u>	<u>\$757,390</u>

The average number of inmates who participated in research during 1976 was 362 per month, earning an average monthly income of \$28.94. Approximately 36 percent of the inmates available for research participated. Inmates may participate in research in addition to receiving compensation for other work at the institution.

CDC's budget for 1975-76 indicated that inmates who participated in the Correctional Industries Program earned an average of \$29.42 per month. Inmates with pay-work positions supported by the General Fund within California Correctional Facilities received an average of \$14.12 per month.

Research Approval Documentation

To monitor any approval process, it is necessary for the approving bodies to adequately document the actions they have taken. We reviewed the research project files at SIMPR, CMF and CDC. The review disclosed numerous cases of missing supporting documentation at all levels

of the research approval process. Through a secondary review of CDC's files, documents supporting research approval were obtained for all projects conducted at CMF between 1973 and 1976.

Chapter 1250 of the California Statutes of 1977 establishes an Institutional Review Board which must approve all research conducted at CMF. The Board should ensure that documentation evidencing approval is maintained at all levels within the research review and approval process to establish accountability.

Research Results

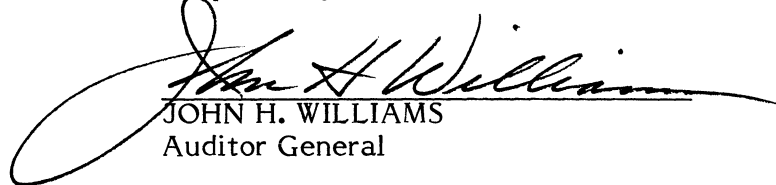
The contract between the State and SIMPR requires that research findings and reports be available to the State on demand. CMF, through its policy statement, requires that the results of research be on file at SIMPR's office, and upon completion of a project requires that the researcher furnish the superintendent with a report of project findings. Our review of SIMPR's and CMF's project files indicates the above requirements are not being enforced. The creation of an Institutional Review Board, which is responsible for evaluating the impact of research conducted at CMF, should ensure SIMPR and CMF compliance with the above requirements.

Review of Research Publications

The Department of Corrections requires that all publications resulting from research conducted at CMF be submitted to the Department for review. The procedure provides the Director with the opportunity to comment, if he desires, upon the contents or findings of the report.

Based upon reviews of department files and discussions with departmental personnel, none of the publications resulting from SIMPR-sponsored research, of which there have been many, have been presented to or requested by CDC for purposes of their review.

Respectfully submitted,



JOHN H. WILLIAMS
Auditor General

October 31, 1977

Staff: Harold L. Turner, Audit Manager
Charles A. Dobson, CPA
Edwin H. Shepherd
J. Peter Bouvier

SOLANO INSTITUTE
FOR MEDICAL AND PHARMACOLOGICAL RESEARCH

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October 31, 1977

Mr. John H. Williams
Auditor General
Joint Legislative
Audit Committee
Suite 750
925 L Street
Sacramento, CA 95814

Dear Mr. Williams:

Dr. James H. Kimbell, Chairman of S.I.M.P.R., has requested that I respond to Draft Reports by your office. Exigencies of his professional office have precluded his personal response. He further apologizes for not being able to attend the meeting of October 31, 1977, and has directed me to represent him.

Your recommendations are well taken and duly noted. SIMPR Board of Directors will cooperate with CMF Superintendent, T. L. Clanon, M.D., in these matters.

In closing, I would like to take this opportunity to commend Mr. Charles Dobson and Mr. Ed Shepherd for their patience in what I know was an extremely trying and difficult task.

Yours truly,



F. R. Urbino
Administrative Director - SIMPR

cc: J. H. KIMBELL, M.D.
FRU:mm

SIMPR
STATEMENT OF REVENUES AND EXPENDITURES
FOR THE YEARS ENDED
DECEMBER 31, 1973 THROUGH 1976
(Unaudited)

	<u>1976</u>	<u>1975</u>	<u>1974</u>	<u>1973</u>
<u>Gross Revenue</u>				
Research	<u>\$286,939</u>	<u>\$532,685</u>	<u>\$370,015</u>	<u>\$331,656</u>
<u>Direct Costs</u>				
Payments to Inmates and Inmate Welfare Fund	141,481	258,974	183,437	173,498
Custodial Coverage Provided by CMF	59,713	57,148	47,403	45,079
Consultant Fees	14,200	56,387	41,751	47,516
Research Supplies	<u>13,044</u>	<u>23,555</u>	<u>12,224</u>	<u>13,591</u>
Total Direct Costs	<u>228,438</u>	<u>396,064</u>	<u>284,815</u>	<u>279,684</u>
<u>Administrative Costs</u>				
Salaries and Wages	43,673	67,907	40,974	43,720
Directors	2,200	950	700	1,200
Travel	5,909	4,682	3,207	3,017
Rent	1,814	2,385	1,911	1,284
Depreciation	8,545	9,497	9,497	9,497
Insurance	3,995	4,456	1,644	1,867
Legal and Accounting	3,600	3,600	3,600	3,600
Office	3,457	5,833	4,770	3,923
Taxes	797	915	814	897
Miscellaneous	<u>817</u>	<u>579</u>	<u>50</u>	<u>374</u>
Total Administrative Costs	<u>74,807</u>	<u>100,804</u>	<u>67,167</u>	<u>69,379</u>
Net Operating Income or (Loss)	(16,306)	35,817	18,033	(17,407)
Interest Income	<u>6,247</u>	<u>4,573</u>	<u>4,850</u>	<u>4,799</u>
Net Income or (Loss)	<u>\$ (10,059)</u>	<u>\$ 40,390</u>	<u>\$ 22,883</u>	<u>\$ (12,608)</u>

PRISON RESEARCH--ORIGIN AND SCOPE

Biomedical research, mainly testing the efficacy of new drugs and vaccines, was conducted in the United States in isolated instances prior to 1934. In 1934 a program to assess the abuse potential of narcotic analgesics was established at Leavenworth Prison. During World War II, prisoners volunteered in large numbers for studies which were viewed as contributing to the national interest. Following the war the support of biomedical research by the government and the public brought an enormous growth to research enterprises, and prisoners served as subjects in many of these new endeavors.

In 1962 the Kefauver-Harris Amendments to the Food and Drug Act established additional requirements for testing the safety and efficacy of all drugs to be sold in interstate commerce. The drug testing requirements established under these amendments required evaluation of the safety of new drugs in normal volunteers under controlled conditions, and prisoners became the population on which much of this testing was performed.

A study conducted in 1976 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research reported that only seven states performed biomedical research in their correctional facilities. This represents a decline in prison research reported by earlier studies.

PRISON RESEARCH--CONDUCTED IN OTHER STATES

The six other states which were reported to be conducting prison biomedical research were contacted during the course of this study. The states contacted were Indiana, Maryland, Michigan, Montana, Texas and Virginia.

Maryland and Virginia

Maryland and Virginia have discontinued all biomedical research in their correctional facilities.

Indiana

All research conducted at the Indiana Reformatory at Pendleton is performed by the medical staff of Eli Lilly and Company. Each project must be submitted to three or more physicians for their review and approval. If approved, the project is presented to the superintendent of the reformatory for his approval. All substances tested are limited to marketed items and/or new drugs which have already been tested on humans. The medical staff of the reformatory must also be kept fully informed on all phases of each research project.

Michigan

Only Michigan based pharmaceutical firms, medical schools and research institutes with established research credibility may be considered as eligible sponsors to conduct research projects. Independent researchers who evaluate drugs on a contractual basis are ineligible to initiate research projects.

The Michigan Corrections Commission has appointed an eight-member Protection Committee to evaluate all pharmaceutical research projects and recommend their approval or disapproval to the Director of Corrections.

The Commission also appointed a six-member Administrative Review Committee to perform at least an annual review of the pharmaceutical testing program. The Director may not approve a research project that has been disapproved by either the Protection Committee or the Administrative Review Committee. However, he may unilaterally disapprove a project even though it was favorably recommended by one of the committees. The ultimate responsibility for pharmaceutical testing in humans rests with the Michigan Corrections Commission and the Director.

Montana

The research conducted in Montana is performed through the University of Montana Foundation's Deer Lodge Research Unit. A permanent facility was constructed on the prison grounds to perform the

studies for private and governmental organizations. All activities are supervised by a full-time physician director specializing in experimental medicine. All projects must be approved by the Board of Review, which consists of the following:

Director of the University of Montana Foundation

Director of Sponsored Programs Administration for the University of Montana

Warden of the Montana State Prison

Medical doctor with knowledge and experience in medical research

Faculty member of the School of Pharmacy, University of Montana

Faculty member-at-large, University of Montana

Clergyman

Attorney

Representative for the prisoner population at Montana State Prison

Texas

Research conducted in correctional facilities in Texas must be approved by the appropriate review committee of the institution with which the researcher is affiliated, prior to submission to the Department of Corrections. An initial review is performed by the assistant director for treatment. The project is then submitted, along with recommendations, to the Institutional Review Committee. The committee forwards a report of their findings to the Director of Corrections. If approved by the Director, the project is presented to the Texas Board of Corrections, which has the final authority to either approve or disapprove all research.

No member of the Institutional Review Committee may be involved in either the initial or continuing review of a research project in which he has a professional responsibility, except as requested by the committee.

Inmate Compensation

The methods of inmate compensation varied greatly among the states. Therefore, it is impossible to compare their methods with California's.

Texas did not provide a copy of their inmate pay scale, but the rates are established by their Institutional Review Committee, whose policy is that inmate compensation shall not be excessive to the extent that it may be construed to be coercive.

The inmate pay scales for SIMPR, Indiana, Michigan and Montana are presented in Appendices D, E, F and G, respectively.

BASIC INMATE PAY SCALE
SOLANO INSTITUTE FOR MEDICAL
AND PHARMACOLOGICAL RESEARCH

Doctor Visit	\$.55
Lab - Blood Draw	2.75
24-hour Urine Carry	1.65
24-hour Stool Collection	1.65
EKG	1.65
EEG	1.65
X-Ray	1.50
X-Ray (w/Barium Enema)	5.00
Eye Exam	1.50
Eye Exam (w/Pupil Dilatation)	3.00
Endoscopy	25.00
G.I. Tube	12.50

INMATE PAY SCALE

INDIANA REFORMATORY
PENDLETON, INDIANA

<u>Inmates Serving as Subjects</u>		<u>Recreation Fund</u>
A. On Lilly, MCGH, Ward	\$50 per month (pro-rated at \$1.66/day) (Minimum payment of \$25 if sent back for physical reasons)	
B. On Lilly-Pendleton Ward	\$30 per month (pro-rated at \$1/day)	Equal amount
C. On cell block	\$0.50 per day	Equal amount
D. As outpatients at Pendleton Hospital		Equal amount
1. Injections	\$1.00	
2. Vena puncture:		
1 tube blood	\$0.50	
more than 1 tube	\$1.00	
3. Urine samples when blood is not obtained:		
single specimen	\$0.50	
multiple specimens	\$1.00	
E. At the discretion of the physician and with the approval of the Superintendent of the Indiana Reformatory, the inmate's remuneration for participation may be adjusted in accordance with the possible hazard or with the potential discomfort associated with the procedures involved.		

INMATE PAY SCALE
MICHIGAN
DEPARTMENT OF CORRECTIONS

BLOOD SAMPLES:

1- 10 cc.	\$ 1.00
11- 20 cc.	2.00
21-200 cc.	3.00
201-500 cc.	5.00

URINE SAMPLES:

Aliquot	.25
24-hour Collection	1.00

FECAL SAMPLES:

Aliquot	.25
24-hour Collection	1.00

MEDICATION:

Oral Medication	.25
Injections (I.V., I.M., I.D.)	1.00

MISCELLANEOUS:

Physical Examination	1.00
Psychiatric Examination	
-If on call	.50
-If not on call	.75
Bone Marrow Aspiration (Hip or Sternum)	12.00
Hospitalization (Per Day)	1.00
Special Diet (Per Day)	1.00
Skin Testing (Series of 30)	7.50
Synovial Fluid Withdrawal	12.00
Callback for Observation	.25
E. C. G.	1.00
X-Ray (Per Film)	1.00
Gastric Samples	
-1st hour	8.50
-Each additional hour	3.00
Intravenous Injections (Per Hour)	2.00

INMATE PAY SCALE
UNIVERSITY OF MONTANA FOUNDATION
DEER LODGE RESEARCH UNIT

ROUTINE SAMPLING PROCEDURES:

Blood samples (In-and outpatient basis: paid on an individual basis, per individual drawing):

1 - 20 cc.	\$1.00
21 - 100 cc.	2.00
101 - 200 cc.	3.00
201 - 300 cc.	4.00
301 - 500 cc.	6.00

Urine samples:

Morning sample	0.25
24-hour collection	1.00

Fecal samples:

Outpatient basis:

Bowel movement aliquot	0.25
24-hour collection	1.00

Inpatient basis:

Paid for each bowel movement collected	0.25/stool
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MEDICATION (In-and outpatient basis)

Topical medication	0.50 each time
Oral medication	0.25 each time
Injection (I.V., I.M., or I.D.)	1.00/injection

When drug is being administered for the first time in humans:

Oral medication	0.50 each time
Injections (I.V., I.M., or I.D.)	2.00/injection

CLINIC PROCEDURES:

Fasting (nothing to eat or drink, except water) from 12:00 p.m. until the following morning's clinic procedure is completed	1.00
Physical examination - Routine	1.00
Eye examination - slit lamp, funduscopy, tonometry, acuity	2.00
Vital Signs only	0.25
Special diet (any diet restrictive in nature)	1.00/day
EKG	1.00
Nasal tube placement	2.50
Skin testing (series of 30)	7.50
Confinement to Study Ward (24 hours)	2.00

Gastric sampling procedure:

Placement of gastric tube and for first hour of sampling	5.00
Each additional hour of sampling	1.00/hour
Each "retubing" as required by study design	2.00
Return of gastric sample as required by study design	0.25
Bone marrow aspiration (hip or sternum)	10.00

Glucose tolerance test

Fasting	1.00
Glucose ingestion	0.25
- blood samples paid for on a volume basis, per sample	

MINIMUM PAY:

If for any reason while a trial is in progress and the individual volunteer is not required for testing, medication or other procedures (holding days), he shall be paid a minimum amount of fifty cents (50¢) for such days.

Office of the Auditor General

cc: Members of the Legislature
Office of the Governor
Office of the Lieutenant Governor
Secretary of State
State Controller
State Treasurer
Legislative Analyst
Director of Finance
Assembly Office of Research
Senate Office of Research
Assembly Majority/Minority Consultants
Senate Majority/Minority Consultants
California State Department Heads
Capitol Press Corps