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FACULTY NEWSNOTES

Edited by Debbie Gough

March 23, 1983

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OFFICE OF THE PROVOST

Principles/Procedures on Protection of Human Subjects:

A committee was appointed by the Provost in the spring of 1981 to review an NIMH grant proposal from the School of Nursing in order to satisfy the federal requirement that a committee on human research exist at institutions receiving federal funds. In November, 1981, the Committee on Protection of Human Subjects (CPHS) was formed by the Provost, and it was charged with developing a set of regulations and procedures for the protection of human research subjects for the USD community and with reviewing research proposals submitted to it during this interval. The committee included: Dr. Janet Blenner, Chair, School of Nursing; Dean Ed DeRoche, School of Education; Dr. Dan Moriarty, College of Arts and Sciences; Dr. Evelyn Anderson, School of Nursing; and Dr. Sue Zgliczynski, School of Education.

Working with a preliminary draft provided by the Provost, along with federal regulations, those adopted by professional organizations, and ones used at other universities, the committee generated the principles and procedures document attached to these Newsnotes. The document outlines procedures which researchers are to follow when using human subjects. The goal of CPHS review of research proposals is to insure that researchers conform to the principles for protecting the rights and welfare of their human subjects, as outlined in the draft, and to document that conformity should our procedures be examined by some regulatory agency.

The review is in no way related to evaluation of the merit of the proposed research and is not intended to hamper research activities, nor does it remove primary responsibility for ethical research practice from the investigator. On the contrary, it is intended to focus the researcher's attention on ethical considerations. The existence of the committee on campus recognizes the role of research at an academic institution and will hopefully foster such activity.

Dr. Lynne Small, Chair, University Senate, has indicated that she will formally propose the attached Principles/Procedures to the University Senate for adoption. The draft Principles/Procedures have already been circulated to all the Schools and academic departments, and the CPHS has revised the draft in accordance with modifications suggested by faculty. Anyone who has further suggestions could send them in writing to Dr. Janet Blenner, Committee Chair, by Thursday, April 7, 1983.

Analysis of Student/Faculty Statistics:

I am attaching at the back of these Newsnotes, for your information, two pages summarizing and interrelating for the current semester (Spring, 1983) courses offered, class enrollments, average students per course, student units generated, FTE faculty, student/faculty ratio, etc. As many of you know, we have published comparable information each fall semester since 1972 (Newsnotes of December 15, 1972; November 2, 1973; November 8, 1974; November 14, 1975; November 17, 1976; November 9, 1977; November 17, 1978; November 16, 1979; October 31, 1980; November 6, 1981; and November 19, 1982), as well as spring semester data since 1974 (Newsnotes of May 24, 1974; May 30, 1975; April 23, 1976; April 14, 1977; May 15, 1978; April 24, 1979; April 11, 1980; April 10, 1981; and April 8, 1982).

The student/faculty statistics need some explanation, and I ask you to read the data in the light of the annotations which follow:

1. The data is based on enrollment statistics received from the Registrar's Office on February 16, 1983.
2. Figures are comparable to those of prior years, since the same basis was used for figuring out the statistics. There was one exception. In the School of Education, all units taken by graduate students (and paid for as such) have been listed in the graduate column, even though several undergraduate-numbered courses are open to and taken by graduate students; prior to Fall, 1975, units were listed in the column appropriate to the course number.
3. The official student/faculty ratio figure is Column N - or Column M if one does not include sabbaticals. Both Columns M and N include administrative time (such as department chairships) and any special project time as well as instructional time. However, Column L - which gives an instructional student/faculty ratio - is included also, since the comparison between Column L and Columns M and N indicates the effect of faculty administrative time on the student/faculty ratio.
4. The administrative time of the Deans and Associate Deans of the five schools/college is NOT included anywhere in the chart; their instructional time is included, in that the student units are counted, but the FTE faculty is not increased by virtue of the fact that a Dean or Associate Dean is teaching a course.
5. Where a faculty member is teaching in the External Degree program as part of his or her regular semester's faculty load, the proportion of teaching time in the External Degree program has been removed from the department and discipline column and added to the External Degree line.

6. The various national, regional, and professional groups to which the University belongs (such as the American Bar Association) often specify particular formulae for computing student/faculty ratios. Computations according to these formulae cannot be ignored, especially in the case of an accrediting body. But computations according to these formulae sometimes differ from the computations on the attached sheets, which are based on the number of student units and full-time equivalent faculty. As soon as we are aware of differing student/faculty ratios computed according to formulae of various associations, we will communicate them in these Newsnotes.
7. Since Fall of 1976, we have used a formula for determining the number of classes, and hence the average students per class, for laboratory courses which counts each lab section of a course with several labs as a class section but does not count the lecture as a class. Courses with lecture and single associated lab are counted as one class. This only affects figures in Columns A and C for those departments offering lab courses.
8. For some Honors Program and interdisciplinary courses, each faculty member received three units of faculty load credit and student credit hours were divided evenly among the two disciplines which the faculty members represented.

Note: One key element in student/faculty statistics is not reflected on a chart such as this, namely, the advising load. A discipline may have a fairly high student/faculty ratio, but a small number of majors for its faculty members to advise. Another discipline may have the same or smaller student/faculty ratio, along with a hundred or more majors to advise.

OFFICE OF STUDENT AFFAIRS

Reminder:

USD night at the San Diego Symphony: Wednesday, April 13, 1983 at 8:00 p. m. in the Civic Theatre. Tickets are no longer available on campus (sold out!), but you may contact Barbara Schmitz in Student Affairs if you are interested in having her order tickets for you.

VARIA

Dr. Hugh Ellis, Biology Department, presented a paper entitled "Temperature Regulation in Hawaiian Red-footed Boobies," at the annual meeting of the American Society of Zoologists held last December in Louisville, Kentucky. The paper, co-authored with Drs. G.C. Whittow and T.N. Pettit of the University

of Hawaii and Dr. M. Maskrey of the University of Tasmania (Australia), is the result of part of the research Dr. Ellis has been conducting in Hawaii on seabird energetics.

Dr. Mario Picconi, School of Business, and Dr. Charles L. Olson of Governors State University, who was a Visiting Associate Professor at USD in 1980-81, have published a textbook entitled Statistics for Business Decision Making.

Dr. John Schindler, Chemistry, has acquired an Aminco-Keirs Spectrophosphorimeter from UCLA storage which had been superceded by a more advanced, "Research-Grade" Spectrofluorimeter. Pending routine maintenance and replacement of minor components, he intends to use the instrument both in research and teaching. The same model cost \$6800 in 1976, although this one may be 10 years older, and has the capability of being upgraded considerably.

Dean Joseph Pusateri has been asked to serve as a consultant on career options in the Liberal Arts for the American Conference of Academic Deans. He has also been invited to author the section on Broadcasting for the forthcoming Encyclopedia of Southern Culture funded by the National Endowment for the Humanities. On February 12, he served as a panelist in the session on "The Teaching of Business History" at the first annual meeting of the Western Association for Interdisciplinary Studies in Business. He is currently on sabbatical (more or less) completing a new book, Business Enterprise in America: A History, which will be published by Harlan Davidson Inc. in December, 1983.

Prof. Timothy Erwin, English Department, delivered a paper at the annual meeting of the Western Society for 18th Century Studies in San Francisco on February 19: "Form and Context in The Life of Savage: Locke, Pope and Voltaire." A brief related publication, "The Life of Savage, Voltaire and the Neglected Letter," will appear early next year in Notes and Queries (Oxford).

Dr. Janet Blenner, School of Nursing, went to Denver, Colorado March 21-23 to attend a National League for Nursing Site Visitor Training Program.

Dr. Dennis Rohatyn's paper, "Peirce and the Defense of Realism" has been published in Transactions of the Charles S. Peirce Society, Vol. 19, No. 1 (Winter, 1983), 45-61. Another paper, "¿por que moore levanto las manos?" has been published in Logos (Mexico City), Vol. X, No. 30 (Sept.-Dec., 1982), 115-123, as translated by Dr. F.A. Padilla of Universidad La Salle.

Rosemary Goodyear, Assistant Professor in the School of Nursing, has been chosen to co-lead a Sino-American Clinical Study Group of Family Nurse Practitioners to the People's Republic of China. The Educational leader will be Loretta Ford, R.N., Ed.D., Dean, Director of Nursing, University of Rochester, School of Nursing, Rochester, New York. The Clinical Study Group will focus on the changes, trends and current practice of nursing in China in contrast with the United States. Field visits to hospitals, clinics, universities, and the Chinese Nursing Association are some of the activities planned during the two week study tour.

Dean Ed DeRoche is serving on the higher education committee that will provide information to Dr. Tom Payzant's Project Rainbow. This project is designed to improve achievement in four selected schools in the city.

Dr. DeRoche has been elected to Scholia, one of San Diego's oldest "town and gown" clubs, and is serving on a committee appointed by the Bishop to help him prepare a pastoral letter on Catholic education and educators.

Dr. James Hottos, Department of Political Science, has published a review of Kevin Phillips' Post Conservative America in the March, 1983 issue of The American Political Science Review. Dr. Hottos has also organized sessions on "Voting and Voting Choices" and "Social Scientists Look at the Computer Revolution" for the upcoming meeting of the Western Social Science Association.

An article by Dr. Jack Morrison, Professor, Counselor Education, entitled "Teenage Pregnancy" appeared in the September issue of Clearing House.

A paper entitled "Adolescent Insomnia" was presented by Dr. Morrison in February in Los Angeles at the yearly convention of the California Personnel and Guidance Association.

On January 26, Dr. Morrison served as a reactor at a panel presentation at Spreckels Elementary School on the topic "Kiwanis Club - Student Counseling Center Partnership." On the panel were Ms. Chris Pare and Ms. Connie Strohbehn, counselors for the San Diego City school system; Mr. Len Kidd, Principal of Spreckels; Dr. Tom Payzant, Superintendent of San Diego Unified Schools; and retired Admiral Edwin Miller representing the Kiwanis Club. The Downtown Kiwanis Club has donated \$5000 in support of student counseling centers in elementary schools. The audience had the opportunity to observe this school's approach to integration by utilizing group counseling sessions.

Spring, 1983

University of San Diego

STUDENTS

FACULTY

SCHOOL / COLLEGE	Courses offered			Total class enrollment			Avg. students per course			Student units generated			Instructional FTE by level			Instr'l FTE	FTE Fac.	FTE fac. In satib.	Avg. fac. load	Stu. un. per inst'l FTE	Instructional s/f ratio by level			Instr'l s/f ratio	s/f ratio	s/f ratio including sabbatical
	A			B			B ⁺ A ⁻ C			D			(12 units) E								(12 un) F	G	H			
	LD	UD	Grad	LD	UD	Grad	LD	UD	Grad	LD	UD	Grad	LD	UD	Grad	LD	UD	Grad	LD	UD				Grad	L	M
Arts & Sciences	256.4	159.11	10.49	6715	3146	106	26.2	19.8	10.1	20,078	9237	318	64.19	42.3	2.62	109.11	112.44	117.4		272	20.9/1	14.6/1	8.1/1	18.1/1	17.6/1	16.8/1
Anth/Soc.	15	12		276	166		18.4	13.8		828	496		3.75	3.0		6.75	7.0	8.0	12	196	14.7/1	11.0/1		13.1/1	12.6/1	11.0/1
Biology	11	11		228	183		20.7	16.6		763	619		3.9	4.25		8.15	8.48	8.48	11.9	170	13.0/1	9.7/1		11.3/1	10.9/1	10.9/1
Comp. Sci.	10	1		241	11		24.1	11.0		723	32		2.7	.25		2.95	3.20	3.20		256	17.9/1	8.5/1		17.0/1	15.7/1	15.7/1
English	29	14.71	1.29	752	400	14	25.9	27.2	10.9	2246	1153	42	7.5	3.76	.32	11.58	11.83	12.83	12	297	20.0/1	20.4/1	8.8/1	19.8/1	19.4/1	19.4/1
Environ.St.	4			70			17.5			210	2		1.0	.17		1.17	1.17	1.17		181	14.0/1	-		12.0/1	12.0/1	12.0/1
Fine Arts	23.4	19.6		548	297		23.4	14.1		1536	744		4.95	4.7		9.65	9.90	9.90	12	236	20.7/1	10.6/1		15.8/1	15.4/1	15.4/1
For. Lang.	31	10		629	118	2	20.3	11.8		1887	352	6	7.75	2.33		10.08	10.33	10.33	12	223	16.2/1	10.1/1		14.7/1	14.4/1	14.4/1
History	12	14.8	2.2	488	294	25	40.7	19.9	11.4	1464	881	75	3.0	3.7	.55	7.25	7.50	7.50	12	334	32.5/1	15.9/1	9.1/1	22.3/1	21.5/1	21.5/1
Math	38	6		1011	73		26.6	12.2		3111	219		9.5	1.5		11.0	11.25	11.25	12	303	21.8/1	9.7/1		20.2/1	19.7/1	19.7/1
Philosophy	21	20		671	449		32.0	22.5		2013	1347		5.5	5.25		10.75	11.0	12.0	12	313	24.4/1	17.1/1		20.8/1	20.4/1	18.7/1
Phys. Sci.*	17	10		380	100		22.4	10.0		1034	248		4.14	2.97		7.11	7.36	9.36	11.7	180	16.7/1	5.6/1		12.0/1	11.6/1	9.1/1
Pol. Sci.	9	11	2	333	274	35	37.0	24.9	17.5	999	813	105	1.75	2.5	.50	4.75	5.0	5.0	12	404	38.0/1	21.7/1	14.0/1	26.9/1	25.6/1	25.6/1
Psychology	15	10		335	317		22.3	31.7		1005	881		3.75	2.92		6.67	6.92	6.92	12	283	17.9/1	20.1/1		18.9/1	18.2/1	18.2/1
Rel.Studies	21	19	5	753	484	30	35.9	25.5	6.0	2259	1450	90	5.0	5.0	1.25	11.25	11.50	11.50	12	338	30.1/1	19.3/1	4.8/1	22.5/1	22.0/1	22.0/1
Business Adm.	31	71	27	1019	2087	604	32.9	29.4	22.4	3057	6253	1812	8.42	18.5	8.42	35.34	38.17	38.17	12	315	24.2/1	22.5/1	14.3/1	21.0/1	19.4/1	19.4/1
Education	3	7.2	24.8	97	236	393	32.3	31.9	15.8	194	960	1444	.75	3.1	8.6	12.45	14.37	15.37	12.1	209	17.2/1	20.6/1	11.2/1	13.9/1	12.1/1	11.3/1
External Deg.			2			25			12.5			75			.58	.58	.58	.58		129			8.6/1	8.6/1	8.6/1	8.6/1
Law			104			4123			39.6			11974			48.5	48.5	50.3	54.3		247			16.5/1	16.5/1	15.9/1	14.7/1
Naval Science	1			14		14				42																
Nursing		9	18	202	192		22.4	10.7		655	560		4.5	6.1	10.6	11.1	11.1	11.5	115		9.7/1	6.1/1	7.6/1	7.3/1	7.3/1	7.3/1
Paralegal Stu.		5		14			2.8			42																

*Most labs counted as separate classes.

Spring, 1983

University of San Diego		STUDENTS												FACULTY																		
		Courses Offered			Total class enrollment			Avg. students per course			Student units generated			Instr'l FTE by level			Instr'l FTE	FTE Fac.	FTE fac. in. sabb.	Avg. fac. load	Stu. un. per instr'l FTE	Instr'l s/f ratio by level			Instr'l s/f ratio	s/f ratio	s/f ratio Including sabbatical					
		A	LD	UD	Grad	B	LD	UD	Grad	B ÷ A	C	LD	UD	Grad	D	LD						UD	Grad	E				LD	UD	Grad	(12 un) F	G
Arts & Sciences	Anthro-Sociology	5			92	70		18.4	14		275	210		1.25	1.25		2.50	2.62	2.62	12	194	14.7/1	11.2/1		13.0/1	12.4/1	12.4/1					
	Anthropology	5			92	70		18.4	14		275	210		1.25	1.25		2.50	2.62	2.62	12	194	14.7/1	11.2/1		13.0/1	12.4/1	12.4/1					
	Sociology	7			184	96		18.4	13.7		552	286		2.50	1.75		4.25	4.38	5.38	12	197	14.7/1	10.9/1		13.1/1	12.8/1	10.4/1					
Environ. Studies	4		1	70	1		17.5	1		210	2		1	.17		1.17	1.17	1.17	-	181	13.9/1	.7/1		12.1/1	12.1/1	12.1/1						
Fine Arts	Art	7		9	224	170		32	18.9		672	500		1.75	2.25		4.0	4.10	4.10	12	293	25.6/1	14.8/1		19.5/1	19.1/1	19.1/1					
	Music	11.4		7.6	204	72		17.9	9.5		538	139		2.2	1.7		3.9	4.0	4.0	12	174	16.3/1	5.5/1		11.6/1	11.3/1	11.3/1					
	Speech	3		1	100	27		33.3	27		300	81		.75	.25		1.0	1.05	1.05	-	381	26.7/1	21.6/1		25.4/1	24.2/1	24.2/1					
	Theatre Arts	2		2	20	8		10	4		26	24		.25	.50		.75	.75	.75		67	6.9/1	3.2/1		6.7/1	6.7/1	6.7/1					
Foreign Lang.	French	8		4	163	46		20.4	11.5		485	138		2	1		3	3.10	3.10	12	209	16.3/1	9.2/1		13.9/1	13.5/1	13.5/1					
	German	3		2	55	9		18.3	4.5		165	27		.75	.33		1.08	1.08	1.08	-	177	14.6/1	5.5/1		11.9/1	11.9/1	11.9/1					
	Greek	1			4			4			12			.25			.25	.25	.25	-	48	3.2/1			3.2/1	3.2/1	3.2/1					
	Latin	1			10			10			30			.25			.25	.25	.25	-	120	8.0/1			8.0/1	8.0/1	8.0/1					
	Spanish	16		4	377	63	2	23.6	15.8		1131	187	6	4	1		5	5.15	5.15	12	265	18.9/1	12.5/1		17.7/1	17.1/1	17.1/1					
	Italian	2			20			10			60			.50			.50	.50	.50	-	120	8.0/1			8.0/1	8.0/1	8.0/1					
Physical Sci.	Chemistry*	11		8	258	88		23.5	11		637	212		2.56	2.39		4.95	5.08	6.08	11.3	172	16.6/1	5.9/1		11.4/1	11.1/1	9.3/1					
	Physics*	6		2	122	12		20.3	6		397	36		1.58	.58		2.16	2.28	3.28	-	200	16.8/1	4.1/1		13.4/1	12.7/1	8.8/1					

* Most labs counted as distinct sections of a course.

Applicability

The University of San Diego accepts its responsibility to safeguard the rights and welfare of human subjects involved in all research projects conducted at this institution either a) under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities, or b) research conducted at the University of San Diego by an outside agent. It is recognized that the establishment and maintenance of acceptable ethical practice remains the primary responsibility of the individual investigator who is responsible for collaborators, assistants, employees, and students, all of whom incur parallel obligations.

Committee

To this end, the university has created a Committee on the Protection of Human Subjects (CPHS). The committee consists of one faculty member from each of the Schools of Business, Education, Law, and Nursing; two faculty members from the College of Arts and Sciences; one representative from the USD Employees Association; one Administrator; one undergraduate and one graduate student representative; and one representative from the community. All members of the committee will be appointed by the University Administration for a period of two years, and so that half of the membership's terms will expire each year.

Policy

It is the policy of the University of San Diego that:

1. All research proposals involving human subjects will be reviewed and approved by the CPHS.
2. No research investigator shall involve any human being as a subject in research unless the procedures are followed for obtaining the informed consent of the subjects as described below.
 - a. The basic elements of informed consent shall provide the following information to the CPHS and to each subject by means of a written consent form (see Form C):
 - 1) An explanation of the purposes of the research and a description of the procedures.
 - 2) The expected duration of the subject's participation.
 - 3) A description of any reasonable, foreseeable risks or discomfort to the subject.
 - 4) A description of any benefits to the subject.
 - 5) A statement regarding confidentiality of records or reports.
 - 6) A statement regarding compensation or treatment if injury occurs.
 - 7) A statement that participation is voluntary.

b. Modification of this procedure may be permitted by the CPHS when:

- 1) the risk to subjects is minimal;
- 2) the procedure of obtaining informed consent would invalidate the objectives of the research; and
- 3) alternative means of conducting the research are not available or would be less advantageous to the subject.

Where modification is requested, and/or informed consent not needed, a clear statement of reasons shall be included in the proposal, as well as an assessment of the impact on the subject.

3. The university will exercise appropriate administrative overview carried out annually to assure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied and are in compliance with the requirements of federal, state, and local laws.
4. The university's requirements and assurances are applicable when research is conducted at or in cooperation with another entity.
5. The university shall provide each individual conducting or reviewing research involving human subjects with a copy of its policies and procedures.
6. The following are the responsibilities of the researcher:
 - a) The researcher and the appropriate administrator (Dean, Chair) shall determine whether the research involves human subjects and the extent to which the procedure places the subject at risk.
 - b) When it is not clear whether the research involves human subjects at risk, the researcher should assume that the procedure places the subject at risk and follow the provisions applicable when subjects are at risk.
 - c) The researcher and the appropriate administrator shall be responsible for assuring that all research proposals involving human subjects are submitted to the CPHS, accompanied by all required forms.
 - d) The researcher shall submit the research proposal to the CPHS detailing plans for compliance with the policy on informed consent described above, and assuring the CPHS that no human subject will be involved in research prior to meeting those requirements.

- e) The researcher shall be responsible for assuring that documentation of compliance with the policy on informed consent is available.
 - f) The researcher shall assure the university that he/she will not begin the project until the above requirements are met and the researcher receives approval of the project from the CPHS.
 - g) The researcher shall not initiate changes in the research for which CPHS approval has been given without the review and approval of changes by the CPHS.
 - h) The researcher shall provide the CPHS with a brief description of the results of the research and of problems for and benefits to the subjects.
 - i) At the end of the project, the researcher, whenever possible, will provide each subject with a full clarification of the nature of the research and offer to make the results of the study available to him/her. Where specific or humane values justify delaying or withholding such information, the investigator acquires a special responsibility to assure that there are no damaging consequences for the subject.
7. Researchers may request and be granted an expedited review of proposals involving no risk to the subjects. Expedited review shall require the following procedures:
- a) The research proposal shall be reviewed by at least two uninvolved members of the researcher's department/discipline in order to determine that the subjects are at no risk, and that the process for obtaining informed consent will be followed.
 - b) A statement of their findings shall be submitted to the Chair of the CPHS, along with forms A, B and C where applicable, by the researcher.
 - c) The Chair of the CPHS, or his/her designated representative, shall review the materials submitted by the researcher.
 - d) A report of the findings of this review, including a written statement of approval or disapproval of the project, shall be forwarded to the researcher by a time mutually agreed upon by the researcher and the CPHS.

I agree to follow the procedures with respect to safeguarding the rights and welfare of human subjects in this research as established by the University of San Diego.

 Principal Investigator (Signature) DATE

 Committee Approval (Chair's Signature) DATE

UNIVERSITY OF SAN DIEGO

Committee on Protection of Human Subjects

FORM A

To be completed for all research involving human subjects conducted at this institution, and for all research involving human subjects conducted by or under the direction of any employee or agent of this institution in connection with his/her institutional responsibilities, including research conducted at or in cooperation with another entity.

1. Project Title: _____

2. Will the subjects in this research be at risk? YES _____ NO _____

"SUBJECTS AT RISK" means any person who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in research.

3. In the course of this research, will:

a. questionnaires, personality tests or inventories be administered?

YES _____ NO _____

b. subjects include any of the following (check all that apply)?

_____ Minors	_____ Fetuses
_____ Mentally disabled persons	_____ Pregnant women
_____ Prisoners	_____ USD employees or students

c. tissues, body fluids, or other organic materials collected for other purposes be used?

YES _____ NO _____

d. data collected for other purposes be used?

YES _____ NO _____

e. informed consent be obtained in accordance with the university's Human Subjects policy?

YES _____ NO _____

f. the risks to the subjects be outweighed by the potential benefits derived from the research?

YES _____ NO _____

The issues identified above should be discussed in the proposal submitted to the CPHS (see FORM B).

I agree to follow the procedures with respect to safeguarding the rights and welfare of human subjects in this research as established by the University of San Diego.

Principal Investigator (Signature) _____ DATE: _____

Committee Approval (Chair's Signature) _____ DATE: _____

UNIVERSITY OF SAN DIEGO

Committee on Protection of Human Subjects

FORM B

Suggested outline of proposal to be submitted to CPHS. Researchers are encouraged to use this as a checklist to insure that all required information is included. Length of the proposal should not exceed five (5) pages.

1. Background and Purposes of Research

2. Research Methodology

- a. Subject Population
- b. Facilities Where Research Will Be Conducted
- c. Research Procedure or Protocol
- d. Estimated Duration of Subject Participation and of Study

3. Subject's Risks/Benefits

- a. Potential Risks
- b. Risk Management Procedures, Including Informed Consent Procedures
- c. Potential Benefits
- d. Risk/Benefit Ratio
- e. Expense to Subjects

4. Sample Consent Form

 Signature of Principal Investigator or Researcher

 Signature of Witness

UNIVERSITY OF SAN DIEGO

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FORM C: Requirements for Consent Form

The consent form is designed as an agreement for the protection of the rights and welfare of any individual who participates as a subject in research. The following basic considerations should be covered on the consent form used.

1. A statement of the procedures and purposes.
2. A statement of any potential associated risk and/or discomfort for the subject.
3. A statement of any associated benefits for the subject.
4. A statement indicating that participation is voluntary, and that the subject may withdraw at any time.
5. A statement indicating that the subject was given the opportunity to ask questions about the procedure, and that they were answered prior to the subject's agreement to participate.
6. A statement that there is no agreement, written or verbal, beyond that expressed on the consent form.
7. A statement of the duration of subject participation.
8. A statement regarding the confidentiality of the subject.

The consent form should include no exculpatory language by which the subject might waive or release the institution or its representatives, including the researcher, from liability in connection with the research.

The form should conclude as follows:

I, the undersigned, understand the above explanations and, on that basis, I give consent to my voluntary participation in this research.

Signature of Subject or of Parent/Guardian • DATE: _____

Location (e.g., San Diego, California) DATE: _____

Signature of Principal Investigator or Researcher DATE: _____

Signature of Witness DATE: _____