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Human subjects protection in research: Are we doing enough?

Marsha L. Green
University of Nevada Las Vegas

Human Subjects Protection in Research:

Are We Doing Enough?

Prepared by

Marsha L. Green

Bachelor of Science
University of Nevada, Las Vegas
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Examination Committee:
Dr. Anna Lukemeyer, Chair
Dr. William Thompson
Dr. Soonhee Kim
Dr. Joel Wisner

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I. Introduction

Scientific research has produced substantial social benefits but has also posed troubling ethical questions with regard to the use and protection of human subjects. These questions have continued to be in the forefront of all biomedical and social research. The increased education of researchers on the subject of protection of human subjects has become of vital importance in the research world. This education involves program administrators, faculty, staff, students, research participants, and Institutional Review Board Committee (IRB) members. In this study of the University of Nevada, LasVegas (UNLV) human subjects' protection program administration, the question to be answered was: has the increased emphasis on education in the area of human subjects' protection by the newly created Office of Protection of Research Subjects (OPRS) in 1999 at UNLV increased the number of protocols submissions for research conducted over the period of time from 1994-2002**.** My interest in this subject began in 1994 when I was hired to administer the human subjects program in the UNLV Office of Sponsored Programs under the Office of Research. I realized very quickly the responsibility that the Administrator held in educating researchers of the legal requirements and the great importance of human subject protection in research.

Part II of this paper outlines the evolution of protection of human subjects in the research community and explains why it continues to be in the forefront of ethical and moral discussion in today's social and medical research. Literature written in the past twenty to thirty years tells of the effectiveness of increased education, the addition of more complicated ethical questions because of new technology, and the need for a

heightened sense of priority for human subjects' protection in the research world today. Administration of the human subjects' protection program at UNLV has always been high priority since its inception in 1987 under the Graduate College. Intì¥Á2M

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6666666666Þ~666666Þ~666666Þ~66˜666v□66\6reby (we hope) increased awareness of the human subjects legal requirements. Historical data was collected from OPRS on numbers of protocols submitted for the period 1990-2002 for each college at UNLV for evaluation. Part III also discusses other variables that may have affected these submission numbers, i.e., demographic data on growth of numbers of faculty and students and implementation of the UNLV Strategic Planning goals in 1996 and changes in research funding awarded UNLV.

Part IV discusses the research design used to analyze the above questions and also explains the methods used in the gathering and analysis of other information that may have affected the number of protocol submissions. This study was approved by the University of Nevada, Las Vegas Office for the Protection of Research Subjects.

Part V shows an analysis of the data gathered and outlines the findings and conclusions drawn.

II. Literature Review

Why Human Subjects Protection?

The issue of the protection of human subjects in research has been in the forefront of medical and social behavioral research since before World War II. Since that time hundreds of authors have discussed this issue in books, journal articles, educational institutions, conferences, and other media. Below is a timeline of the events during the

past 50-60 years that have been the guiding forces for legal policies, laws, and regulations on human subjects' protection as we know it today:

- 1945 – World War II - The ethical principles and the importance of protection, safety, and confidentiality of research involving human subjects arose in response to the atrocities committed by Nazi scientists during World War II.
- 1946 - The American Medical Association (AMA) adopted its first code of research ethics for physicians outlining principles to be followed in conducting research with human subjects (Institute of Medicine, 2001).
- 1947 - Nuremberg War Crimes Trials. The Nuremberg Military Tribunal developed the Nuremberg Code which set the standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners.
- 1964 - The Helsinki Declaration of 1964 signed (revised in 1975 and 1989). This Declaration clarified the Nuremberg Code and refined definitions and distinctions between research and biomedical practices.
- 1966 - U.S. Public Health Service (PHS) first issued its requirements and guidelines to grantee institutions for safeguarding the rights and welfare of human subjects.
- 1971 - U.S. Department of Health, Education, and Welfare (DHEW) issued Guidelines with regard to human subjects used in research.

- 1973 - The American Psychological Association (APA) established its codes for the conduct of social and behavioral research. New governmental regulations by National Institutes of Health (NIH).
- 1974 – DHEW codified its 1971Guidelines into Federal Regulations 45 CFR 46.
- July 12, 1974 - National Research Act was signed into law creating the National Commission for the Protection of Human Subjects of Biomedical and Behavior Research.
- September 30, 1978 – The Belmont Report by the DHEW outlined the ethical principles and guidelines for the protection of human subjects of research and was made public by the above Commission (DHEW, 1978). The National Commission identified three general judgments relevant to research involving human subjects: *respect for persons, beneficence, and justice*. These form the moral foundation for review and conduct of research involving human subjects. *Appendix Volume I* (Preliminary Papers Prepared for the Commission by Robert J. Levine, M.D. and Basic Ethical Principles Relating to Research Involving Human Subjects) and *Volume II* (Boundaries Between Research and Practice, Risk/Benefit Criteria, and Informed Consent) set forth the criteria used by DHHS in 1991 to establish the "Common Rule" for institutions regarding human subjects used in research (DHHS, http://ohrp.osophs.dhhs.gov). The Report was published in 1979.

- 1981 - Food and Drug Administration (FDA) policy 21 CFR 50 and 51 issued.
- 1991 – DHHS utilized the Belmont Report to issue a new Code of Federal Regulation – 45 CFR 46, "Protection of Human Subjects", also known as the "Common Rule". The Code was amended by the Health Research Extension Act of 1985, Public Law 99-158, on November 20, 1985 to add "Institutional Review Boards: Ethics Guidance Program" and "Fetal Research". It was again amended by the National Institutes of Health Revitalization Act of 1993, Public Law 103-43, on June 10, 1993 for "Certain Provisions Regarding Review and Approval of Proposals for Research". Educational institutions submitting receiving a grant from PHS, UNLV included, must adhere to these regulations (DHHS, http://ohrp.osophs.dhhs.gov/humansubjects/guidance/statute.htm). UNLV takes this one step further and requires all research involving human subjects conducted at UNLV be submitted for review, no matter the funding source (UNLV OPRS, http://www.unlv.edu/Research/OPRS).
- October 1995 - President William Clinton signed an Executive Order which formed the National Bioethics Advisory Commission (NBAC) to investigate the protection of human subjects in research.
- May 1997 - Congress unanimously resolved that "no person in the United States should be enrolled in research without the twin protections of informed consent by an authorized person and independent review of the

risks and benefits of the research" (IM, 2001). NBAC has continued to address issues of research oversight and IRB function.

- May 30, 2000 - DHHS Secretary Donna Shalala issued new initiatives to strengthen oversight of medical research.
- June 5, 2000 - NIH gave notice of mandatory education of researchers. These initiatives required that educational institutions have a training plan in place for all individuals who are considered key personnel responsible for design and conduct of research and/or the use of use of human subjects (humans and/or data and tissues from them). There must be documentation of such training in any Federal grant application by the principle investigator(s) and also key personnel or sites dealing with foreign grants. Institutions were given institutional discretion as to how to meet this new requirement. (Dickstein, SRA WSA Meeting, May 2001).
- April 2002 - DHHS OHRP posted a Quality Improvement Program (QIP) Website (http://ohrp.osophs.dhhs.gov/humansubjects/qip/qip.htm) which reinforces the weight that DHHS places on education and quality of IRB members and researchers. The QIP allows human subjects' protection offices to do a self-administered quality improvement check on its program as to how well it is complying with Federal regulations.

Ethical or Unethical Studies?

The need for enhanced efforts to protect research subjects was emphasized in 1966 when Henry Beecher published an article presenting 22 examples of "unethical or questionably ethical studies" that had appeared in mainstream medical journals (Institute

of Medicine, 2001). In 1972 details of the Tuskegee Syphilis Study in 1932 came to light. In "Tuskegee's Truths: Rethinking the Tuskegee Syphilis Study", Susan M. Reverby evaluated why this study of black men who had been infected with syphilis and then had treatment withheld for experimental purposes became a template by which other experiments are measured and evaluated (Reverby 2000).

In 1973 Bernard Barber, John J. Lally, Julia Loughlin Makarushka, and Daniel Sullivan published their study on "Research on Human Subjects – Problems of Social Control in Medical Experimentation" (Barber, et al 1973). These researchers did two studies on the patterns of ethical standards and practices in the United States at universities and medical facilities. The study outlines the rapid progress in biomedicine and its benefits which was based, in important part, on use of human subjects for research. The authors related that the most undesired effect has been apparent failure to achieve the highest, and in many cases even adequate, standards or professional moral concern and behavior with the human subjects used in this necessary experimentation.

The biomedical research community was joined by professors of law, moral philosophy, and social science, in organized symposia to compose a more accurate view of the problem. In an empirical study of "Number and Proportion of Articles on Human Experimentation by Year and Type of Journal", (Barber, Lally, Makarushka, and Sullivan (1973), it was found that there was a dramatic rise of medical journal articles devoted to facets of this problem. This occurred in 1966 which was about the same time that the PHS first issued its requirements and guidelines to grantee institutions for safeguarding the rights and welfare of human subjects (Barber, et al 1973).

In 1973 Barber, et al, also conducted a National Survey to collect data on two key issues: informed voluntary consent and proper balance between risk and benefit in experiments done with human subjects. Biomedical research institutions were surveyed for a nationally representative sample. The second study was an "Intensive Two-Institution Study, which obtained responses to lengthy personal interviews which were chosen by cluster analysis. The researchers were able to obtain a 72% response rate from a set of representative responses from biomedical researchers who used human subjects.

The researchers found in their analysis that two patterns emerged. "One was that a majority of biomedical researchers using human subjects are very much aware of the importance of informed voluntary consent and that a majority express unwillingness to take undue risk when confronted with hypothetical research." The other is that there is a "significant minority that manifests a different type of pattern, what we call 'more permissive,' in each of these three respects: unawareness of the importance of, or concern with, consent; willingness to take undue risk; and actually doing studies that involve unfavorable risk-benefit ratios". Their study concluded that at that time in the U.S., medical schools had not been successful in the training or even any serious discussion of what such training ought to include on the socialization into the ethics of the use of human subjects. One recommendation from the study was to add a course in biomedical research ethics which would be invaluable not only for future researchers but for those practitioners who have the ethical responsibility for patients who become research subjects. It was shown that continuing education was vital to the protection of human subjects (Barber et al, 1973).

More Training and Education Needed?

The relationship between education and cognitive moral development was studied by George Izzo in his article "Compulsory Ethics Education and the Cognitive Moral Development of Salespeople: A Quasi-Experimental Assessment" published in the Journal of Business Ethics (Izzo, 2001). Izzo found that that there is a direct positive relationship between a "compulsory" education program and cognitive moral development. This outcome helps prove that education can play a vital role in improving the performance of researchers with regard to ethical concerns involving human subjects.

In "Ethics Instruction at Schools of Public Health in the United States" written by Steven Coughlin, Wendy Katz and Donald Mattison, published in the American Journal of Public Health, the authors note that there is increasing interest in developing curricula on public health ethics and providing instruction on ethics and scientific integrity to students enrolled in public health training programs (Coughlin, 1999). Their report discussed a national survey of schools of public health in the U.S. in early 1996 to determine how they addressed ethical issues in public health. They found that most of the schools offered only short courses, seminar series, or invited lectures on ethical topics and most included lectures on ethics topics in other courses. At most schools there were activities that took place outside of formal courses on ethics issues. This curriculum was designed to provide the students with the conceptual abilities and decision-making skills they would need to deal successfully with ethical issues in their own research and practice.

In 2001 the Institute of Medicine (IM) published "Preserving Public Trust – Accreditation and Human Research Participant Protection Programs". This project was

requested by the Secretary of DHHS and was conducted by the National Academy of Sciences (NAS), National Academy of Engineering (NAE), Institute of Medicine (IM), and National Research Council (NRC). It focused on questions of the safety and rights of the participants who share the clinical research enterprise and who are indispensable to its success. The Committee on Assessing the System for Protecting Human Research Subjects suggested accreditation of Institutional Review Boards (IRB), compressing the burdens on IRBs, educating and perhaps certifying investigators, improving research monitoring, and building greater institutional support and infrastructure. It was recommended that greater emphasis be placed on education of IRB committee members, researchers, and participant (IM, 2001).

Is Education the Answer?

This Institute of Medicine publication above identifies educating investigators as the answer to a serious problem arising in human research. Policies dealing directly with investigators are at least as important as improving the review of research protocols. These policies should address "educating them about their roles and responsibilities in the ethical conduct of research, increasing the capacity to monitor ongoing research approved by an IRB, the investigation of infractions, and the enforcement of regulations". Among these, education seems to be the one most likely to have the desired results with the least level of intrusion and the greatest direct impact on overall norms" (IM, 2001).

In an article entitled "Human Research Subject Protections at Issue" by Peter Melkonian published in the August/September 2001 Society of Research Administrators International (SRA) newsletter, Mr. Melkonian quotes Dr. Wendy Baldwin, Deputy Director for Extramural Research at NIH who "believes that universities need to look at

how they have organized their human research subject protections" (Melkonian, 2001). It is not enough for the Federal Drug Administration (FDA) and NIH to monitor human subject protection. Universities must play an active role in the monitoring and education of researchers in the area of conflict of interest and their research subjects.

III. Research Question

It is evident by the strict Federal regulations governing the protection of human subjects that a highly visible educational process must be in place to train researchers to protect human subjects. This study explored the research question of whether the increased emphasis on identified educational efforts by OPRS in 1999 to 2002 was successful in increasing the quantity of human subjects' protocols submitted by UNLV researchers during the time period studied of 1994-2002.

IV. Research Design

This human subjects' program case study explored the research question of whether the increased emphasis on identified educational efforts by OPRS in 1999 to 2002 was successful in increasing the quantity of human subjects' protocols submitted by UNLV researchers during the time period studied of 1994-2002. The research design for this project was that of a case study which involved a combination of interviews for gathering historical program administration information, data collection on protocol statistics, demographical growth statistics of UNLV faculty and students, and research funding granted to UNLV. Information about educational efforts and office history were gathered through interviews with Dr. William Schulze, Director, UNLV Office of Sponsored Programs and Brenda Durosinmi, Human Subjects Administrator, UNLV Office for the Protection of Research Subjects (OPRS). To measure the success of the

program, data was collected concerning numbers of protocols, faculty, students, and grant funding information for the period 1994-2002.

An interview with William Schulze, Director of the UNLV Office of Sponsored Programs, supplied historical information as to the location and evolution of the office which has administered the human subjects' protection program during the past fifteen years. An interview with Brenda Durosimini, Human Protections Administrator, under the Office of the Vice Provost for Research assisted in outlining the educational programs that have been developed since the creation of the OPRS in 1999. Protocol submission data was collected from the OPRS records for each College for the Fall semester of each year over the period September 1994 to May 2002.

There were two causal variables that needed to be controlled during this evaluation. These two variables were studied to find if there was an outside or additional influence on the number of protocols submitted during the period studied.

1. The first variable concerned the effect of increased demographic growth of faculty and students at UNLV during this time period that may have influenced numbers of protocol submissions. The number of faculty and students at UNLV has increased substantially. This increase is likely to have contributed to any increase in protocols submitted. The demographical data used in this comparison were obtained from the "Selected Institutional Characteristics" publications from Fall 1994 to Fall 2001 which are compiled and published annually by the UNLV Office of Institutional Analysis and Planning.
2. The second variable requiring control was the increased emphasis by the Administration for UNLV faculty to increase research efforts and work towards a

higher Carnegie Research rating for the university. This variable was controlled through an analysis of the research funding received by researchers over the same time period. The President's Office through its "Strategic Plan" implemented in 1996 has placed a greater emphasis on the amount of research that should or must be conducted by faculty in their annual workload requirements. The UNLV "Strategic Plan" was reviewed for goals that required greater research effort on the part of faculty. The annual protocol submission statistical data and the two sets of data above (faculty and student numbers and research funding received) were compared and analyzed to discover whether the increased emphasis on human subjects' protection education of UNLV researchers by OPRS was the only effect on the number of protocols submitted or if the two outside variables discussed above were influencing the number of protocol submissions.

The ratio of "protocols submitted" to "actual studies involving human subjects" needed to be studied. However, the "actual number of studies involving human subjects" at UNLV is not easily gathered or measured. Therefore, the ratio of "protocols submitted" to "number of faculty and students" was used as an approximation of this measure.

V. Findings

History of Human Subjects Protection and Educational Efforts at UNLV

From its inception, the program for the protection of human subjects has always been a priority by UNLV Administration and researchers. The timeline for the "Organizational Structure and Educational Efforts" found during this study can be found in Appendix A. A discussion follows regarding the information presented.

In 1987 Dr. William Schulze, present Director of the Office of Sponsored Programs (OSP) at UNLV, was hired by the Graduate College as the Director of Grants and Research Development. In an interview in September 2002, Dr. Schulze stated that administration of the human subjects' protection program came under his position in 1987 and each UNLV department or college was given approval authority for approval of exempt protocols, i.e., those protocols not requiring full IRB Committee review (Schulze, 2002). No other control or administrative review was in place by the Graduate College.

In 1989 Dr. Schulze' title was changed to the Director, Office of Sponsored Programs (OSP) and his position was moved from under the Graduate College to the Office of the Vice Provost for Research. The human subjects' protection program then became centralized under OSP. All protocols were submitted for review and determination of full board, expedited, or exempt review status. If a protocol requires full review by the IRB, it is scheduled for review at a monthly Social-Behavioral or Biomedical Committee meeting review. These protocols involve special protected groups of subjects, such as children, prisoners, pregnant women, etc. If it is expedited status, three members of either committee, depending on subject area, review the protocol. These protocols may involve a more than normal risk to the subject and fall under special categories in the Federal guidelines at 45 CFR 46. Exempt status requires review and approval by the human subjects' program administrator only and does not require expedited or full board review.

Also in 1989 a Sponsored Programs Coordinator (SPC) was hired to assist Dr. Schulze with research administration responsibilities as well as administration of the human subjects program. The program duties of the SPC were to ensure compliance with

DHHS regulations on protocol submission, organize IRB meetings for expedited or full protocol review, approve exempt protocols, train new researchers in human subjects' protection guidelines, and maintain protocol records and reports. These duties were a small part of the position's overall duties; therefore, the program received only "as required" attention to meet regulation requirements.

According to Dr. Schulze, in the late 1980s very little education of faculty or students was done. In the early 1990s with the addition of the SPC position, more education was offered in the form of presentations at New Student Orientations sponsored by the Graduate College and individual graduate and undergraduate level classes and occasionally to a few departments who requested the information be presented at staff meetings to faculty.

In November 1994 the individual in the SPC position was promoted to Assistant Director, OSP and a new SPC was hired and assumed the administration of the human subjects' protection program until September 1999. Because of time and budget constraints and management decisions on educational issues, there was no change in the type or amount of educational presentations offered to faculty and students in the mid-1990s. In September 1999 a new SPC was hired to assume these duties from September 1999 to December 2000.

During the years 1994-1999, all protocols submitted were reviewed by the Sponsored Programs Coordinator (SPC) who was also a voting member of the IRB. It was the SPC's responsibility for reviewing and determining "exempt" or "full board review" status of the protocols. It was her responsibility to ensure "exempt" type protocols met Federal guidelines for human subjects' protection and to approve at that

level with no further review required. In 1999 when the OPRS was created, it was determined that the IRB Chair person needed to review "all" protocols and to also approve exempt protocols. Therefore, this caused a greater administrative workload for the Chair of the IRB and increased the administrative duties by OPRS staff. Since July 2001, protocols are considered either "expedited" (which includes the exempt and expedited categories) or require "full board" review. According to Brenda Durosinmi, Human Subjects Administrator, in 2001 OPRS undertook the task of "developing an on-going plan of education and training and to develop the necessary tools to ensure a seamless communication process with faculty and student researchers." It was during this time period that the application for a separate Federal-wide Assurance (FWA) for UNLV was submitted to OHRP for approval. Approval was received in Spring 2002.

According to Dr. Schulze, a representative from the DHHS Office of Human Research Protection (OHRP) visited UNLV in November 1999 as part of a nationwide audit of higher educational institutions in the U.S. The representative determined that there was a conflict of interest in OSP handling development and submission of proposals for funding and at the same time administering the human subjects' program. Because OSP is responsible for the oversight and submittal of research proposals to numerous governmental and private sources for funding and responsible for the administration of funded projects by UNLV researchers, a separate office was needed for administration of the human subjects' protection program. Dr. Schulze stated in his interview that "more education of researchers is being emphasized because of the fact that OHRP has become an independent agency and restructured the whole compliance area and because of the now required Federal-wide Assurance provisions affecting all government agencies."

Federal policy requires each entity utilizing human subjects in research to enter into a binding commitment to minimum standards for the protection of human subjects BEFORE research begins. An Assurance is needed whenever faculty, staff, or students (1) intervene or interact with living individuals for research purposes or (2) obtain, release, or access individually identifiable private information for research purposes. In 1987 UNLV received approval for its program under a Multiple Program Assurance of Compliance (MPA) (#M1164) with DHHS (http://ohrp.osophs.dhhs.gov/irbasur.htm). The MPA was under an umbrella agreement for all of the University and Community College System of Nevada (UCCSN) with administration by the University of Nevada, Reno. The MPA was jointly held with the Department of Veterans Affairs, Lougaris Medical Center and Sierra Biomedical Research Corporation (FYI newsletter, July 2002). Under the terms of the MPA, all research involving human subjects must be reviewed for compliance to 45 CFR 46 prior to application for Federal funding or the initiation of the project. UNLV expanded this requirement to all research involving human subjects conducted by faculty or students whether government funded or not. The approved DHHS MPA for UCCSN required that UNLV follow the 45 CFR 46 Federal guidelines and that two Institutional Review Boards (IRB) – the Social/Behavioral Sciences IRB and the Biomedical Sciences IRB – be created. In 1999 new Federal regulations required that each legally separate entity which engages in federally supported human subject research must acquire its own Assurance. In June 2002 UNLV received its individual Federal-wide Assurance (FWA) as a separate entity from the UCCSN MPA (O.R., "FYI", July 2002).

In January 2000 the Office for the Protection of Research Subjects (OPRS) was created under the Office of Research and a Graduate Assistant was hired to handle the program as a unit separate from OSP. In July 2001 Ms. Brenda Durosimni was hired as the Human Protections Administrator, a full-time professional staff member, to administer the program. In addition a part-time professional staff assistant was hired to assist her.

OPRS serves as the clearinghouse for all information and actions necessary for institutional compliance with these Federal requirements (UNLV OPRS, (http://www.unlv.edu/Research/hsindex.html). This office is also responsible for the educational program for ensuring all individuals conducting research at UNLV are given every opportunity to learn the correct procedures and regulations governing their use of human subjects in their research.

In an interview with Ms. Durosinmi in September 2002, she stated that several goals were accomplished during her first year as Administrator from July 2001 to May 2002 (see Table 1 above). Ms. Durosinmi stated that "Investigators are informing the participant more in the way of informed consent and display a better understanding of the compliance issues faced by institutions, faculty, and students. A new culture of compliance has been adopted by researchers as a result of training as directed by OPRS."

The problem area of a more comprehensive training plan has been addressed by the new Collaborative IRB Training Initiative (CITI) training components coming in January 2003. The CITI includes 13 parts each focused on a different aspect of bio-ethics and human subjects' research. Each part, developed by experts in the "IRB community" has an associated quiz. The software maintained at the University of Miami, compiles the

quiz scores. The institution specific training data is forwarded to the respective administrator at the participating institutions on a regular basis. The institution can decide what score is sufficient to pass the course. The individual institution will also distribute certificates or letters of completion based on the predetermined level of achievement. This will replace the NIH certification program in place at present.

Ms. Durosinmi also stated that the new OPRS web site due for completion in December 2002 will offer additional support and assistance to researchers to include new forms, links to additional research sites and information, protocol status database, and an array of useful information for the researcher. She stated "the goal is to accommodate the researcher to insure protection for human subjects and assist them to comply with federal compliance statutes and university policy." Future education and training is being discussed and planned by OPRS. In the next few years expected research from the School of Dentistry and the Biotechnical Center will increase protocol preview numbers for OPRS and the IRB. According to Ms. Durosinmi, additional education and training for those researchers involved in these educational areas will be implemented in the future to meet this demand. Electronic protocol status tracking is being developed to allow researchers to check status of protocols on the OPRS web page (http://www.unlv.edu/Research/OPRS).

In reviewing the history of the human subjects' protection program and the educational efforts at UNLV, one can see that the level of education effort went through a period of expanded effort in July 2000 with the creation of the OPRS and hiring of the Human Protections Administrator. If these efforts are successful, you would expect to see an increase in protocol submission after the increased educational efforts by OPRS began

in July 2000. The information presented below regarding faculty and student protocol submissions is an attempt to ascertain whether these efforts have worked.

Patterns of Submissions

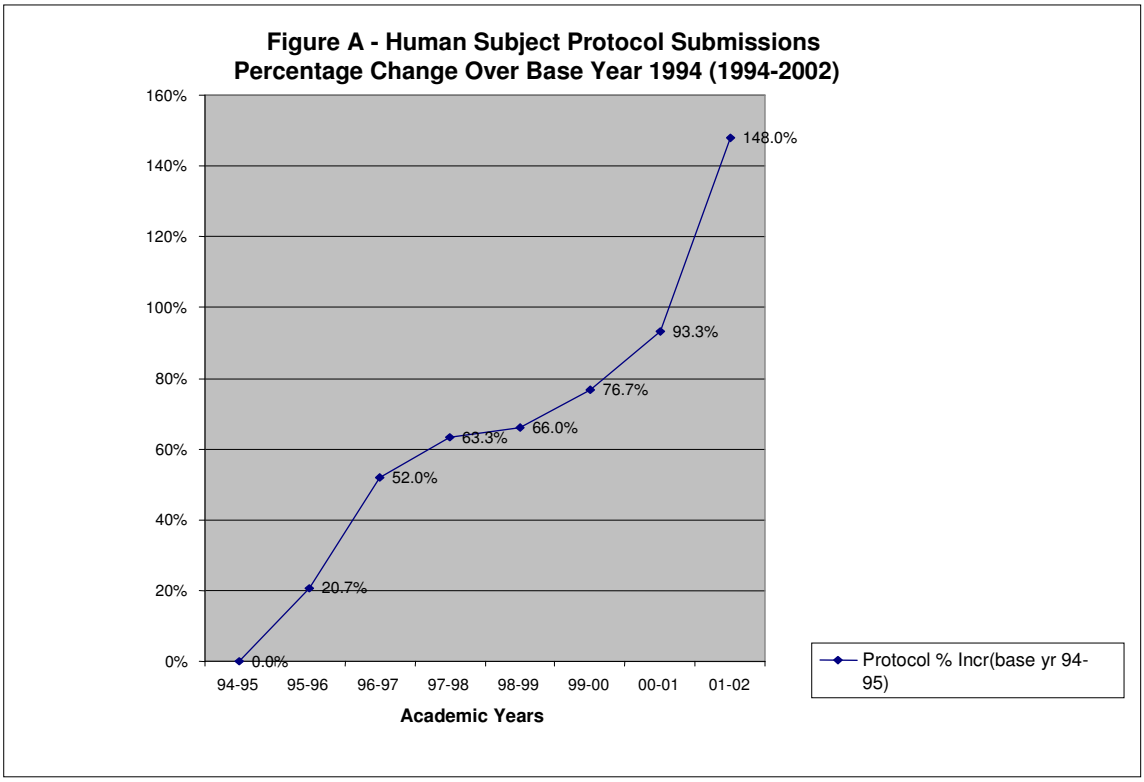
Table 1 below includes the "Protocol Submission Data (May of Calendar Year - Annual Totals) for All Protocols" gathered from OPRS records. Figure A below displays that data in graph format, "Human Subject Protocol Submissions Percentage Change Over Base Year 1994 (1994-2002)". Annual reports for submissions are from May 1 to April 30th of the next calendar year.

Figure A clearly demonstrates that the growth of the number of human subject protocol submissions has grown at a dramatic rate from 150 protocol submissions in the 1994-1995 academic year to 372 submissions in the 2001-2002 academic year or a 148% overall increase in protocol submissions. One can see a fairly large percentage increase in protocol submissions from spring semester ending 1994 to spring semester ending 1998 with an increase of 63.3 percentage points over that three-year period. However, the largest jump is from spring semester ending 1999 to spring semester ending 2002 from 66.0% to 148.0% or an increase of 82 percentage points. Another rapid increase can be seen in 2000-01 to 2001-02 with 54.7 percentage points. This last increase suggests that the OPRS' concerted educational efforts may have had an effect on protocol submissions by researchers. However, two other factors – demographic growth in faculty and students and increased emphasis on research by the Administration – may have had some role in the increase in protocol submissions. These factors are examined in the next section.

Table 1 - Protocol Data (May of Calendar Year - annual totals) - All Protocols

	94-95	95-96	96-97	97-98	98-99	99-00	00-01	01-02
Social/Behavioral Board	21	40	46	25	47	22	53	91

Biomedical Board	12	3	5	7	7	18	23	43
Social/Behavioral Expedited	117	137	173	208	185	220	209	206
Biomedical Expedited	0	1	4	5	10	5	5	32
Total Protocols	**150**	**181**	**228**	**245**	**249**	**265**	**290**	**372**
		31	**78**	**95**	**99**	**115**	**140**	**222**
Protocol % Incr(base yr 94-95)	**0.0%**	**20.7%**	**52.0%**	**63.3%**	**66.0%**	**76.7%**	**93.3%**	**148.0%**
Table 1, continued…	**94-95**	**95-96**	**96-97**	**97-98**	**98-99**	**99-00**	**00-01**	**01-02**
All Social/Behavioral	138	177	219	233	232	242	262	297
All Biomedical	12	4	9	12	17	23	28	75
Total Protocols	150	181	228	245	249	265	290	372
Number Increase over base yr '94	**0**	**31**	**78**	**95**	**99**	**115**	**140**	**222**
% Protocol # Incr over base yr '94		**20.7%**	**52.0%**	**63.3%**	**66.0%**	**76.7%**	**93.3%**	**148.0%**
Percentage Social/Behavioral	92.0%	97.8%	96.1%	95.1%	93.2%	91.3%	90.3%	79.8%
Percentage Biomedical	8.0%	2.2%	3.9%	4.9%	6.8%	8.7%	9.7%	20.2%
Faculty Submissions	34	69	89	73	91	121	144	240
Student Submissions	116	112	139	172	158	144	146	132
Total Protocols	*150*	*181*	*228*	*245*	*249*	*265*	*290*	*372*
Number Faculty Increase		**35**	**55**	**39**	**57**	**87**	**110**	**206**
% Faculty Increase over base yr '94		**102.9%**	**161.8%**	**114.7%**	**167.6%**	**255.9%**	**323.5%**	**605.9%**
Number Student Increase		**-4**	**23**	**56**	**42**	**28**	**30**	**16**
% Student Increase over base yr '94		**-3.4%**	**19.8%**	**48.3%**	**36.2%**	**24.1%**	**25.9%**	**13.8%**
Percentage Faculty Submissions	22.7%	38.1%	39.0%	29.8%	36.5%	45.7%	49.7%	64.5%
Percentage Student Submissions	77.3%	61.9%	61.0%	70.2%	63.5%	54.3%	50.3%	35.5%



Demographic Growth at UNLV

UNLV has seen unprecedented growth in numbers of students attending classes and in the numbers of faculty and staff employed by the State of Nevada in the past ten to twelve years. Initially a comparison of the time period 1990-2002 was to be utilized for this study. However, while visiting OPRS to collect protocol submission data, it was found that information for the earlier years of 1990-1994 were no longer available. Therefore, the period of time covered for this comparison is the academic year beginning Fall1994 and ending June 2002.

Figure B, entitled "Percentage Growth Change of Faculty Over Base Year 1994 (1994-2001)", shows the gradual and sometimes dramatic increase of faculty growth at UNLV. Faculty numbers increased 18.2% from the base year of Fall1994 to Fall 2002.

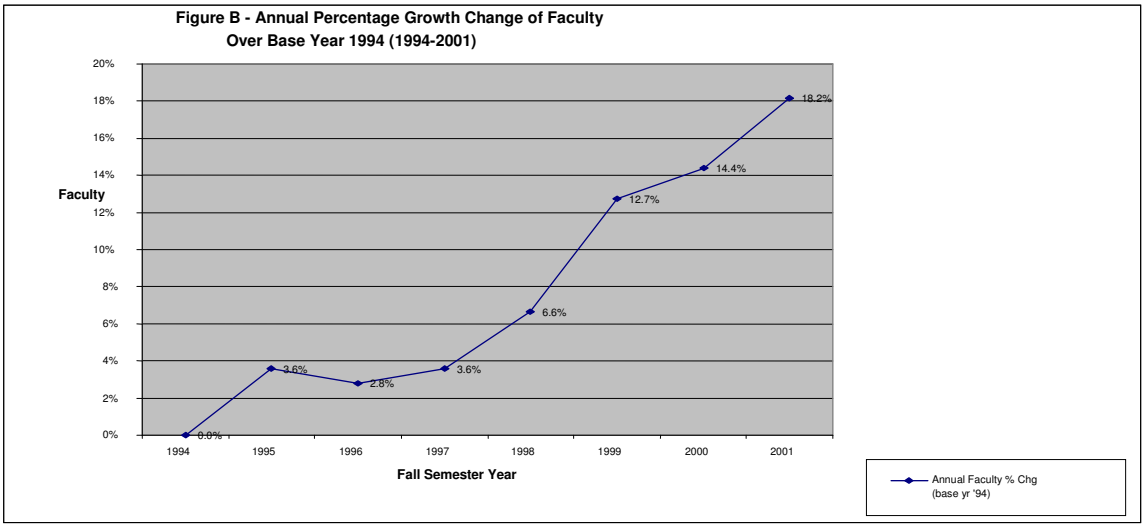
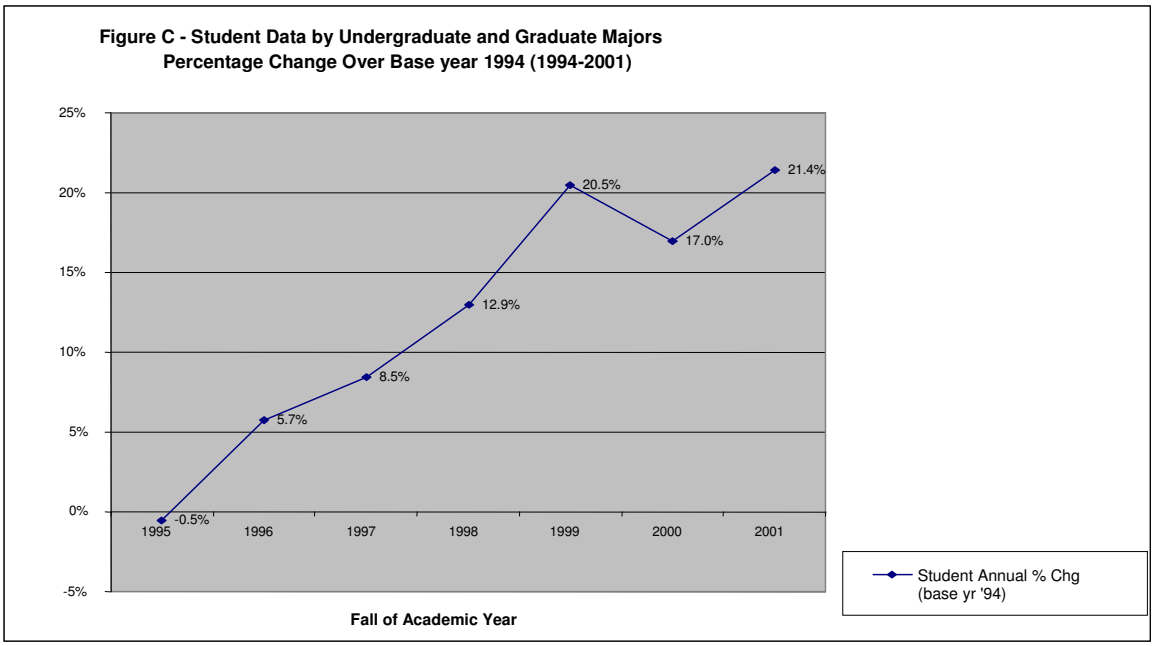


Figure C, entitled "Student Data – All Students (by Undergraduate and Graduate Majors) Percentage Change Over Base Year 1994 (1994-2001)". From base year 1994 there was a decrease of .5% to 1995 and then a continual increase between 1995 and 1996 reaching 20.5% growth in 1999 over the base year 1994. In 2000 UNLV saw a decline in student population of approximately 3.5% from 1999 but then jumped back up in 2001 for an overall increase of 21.4% over 1994.



To control for the impact of faculty growth, a ratio of the number of faculty proposals to number of faculty was calculated. A comparable ratio was created for student protocols. Figure D displays the results. This data indicates that the increase of faculty submission has grown at a much greater rate (33%) than the student submissions (.6%) and total combined submissions (1.5%). This tells us that some variable is clearly affecting the protocol submission rate of *faculty* in the overall period of 1994-2002. Moreover, there is a striking increase from school year 00-01 to 01-02. These data suggest that the growth in faculty is not responsible for all of the growth in protocol submissions. Further, the substantial increase after the school year 00-01 suggests that the educational efforts may have had some impact.

The ratios of student protocol submissions to student numbers held steady since 1994 showing a small decrease overall. The ratio of student and faculty numbers of total protocol submissions to numbers of students and faculty shows a very gradual increase

university-wide in protocol submissions over 1994.

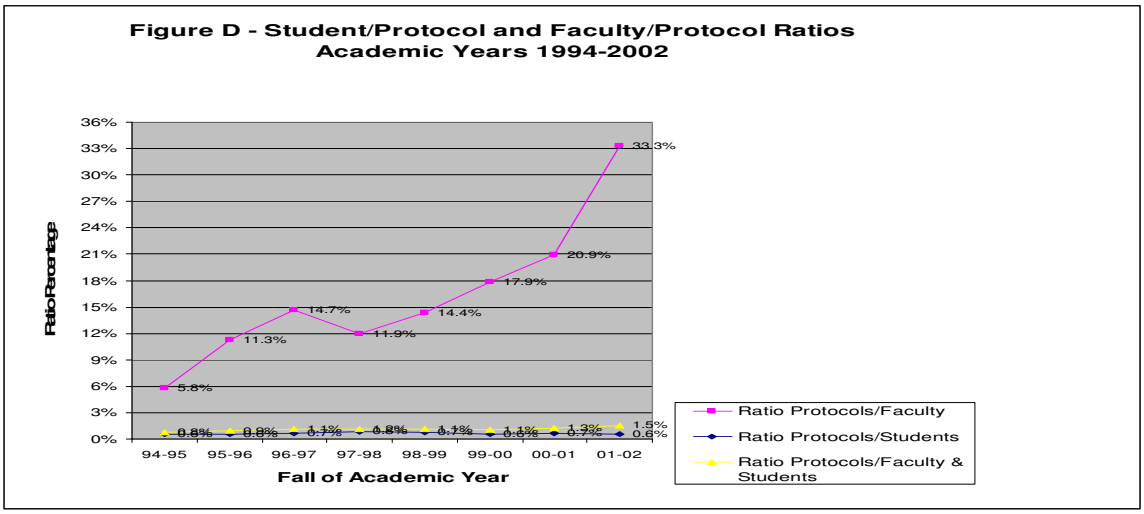


Table 2 shows the statistical data that generated Figure D above.

Table 2– Ratio of Protocol Submissions to Faculty and Students (1994 to 2001)

	94-95	95-96	96-97	97-98	98-99	99-00	00-01	01-02
Protocols Submitted by Students	116	112	139	172	158	144	146	132
Number of Students	18,554	18,456	19,683	20,272	21,312	23,337	22,342	23,618
Ratio Protocols/Students	**0.63%**	**0.61%**	**0.71%**	**0.85%**	**0.74%**	**0.62%**	**0.65%**	**0.56%**
Protocols Submitted by Faculty	34	69	89	73	91	121	144	240
Number of Faculty	590	612	607	612	632	676	689	721
Ratio Protocols/Faculty	**5.76%**	**11.27%**	**14.66%**	**11.93%**	**14.40%**	**17.90%**	**20.90%**	**33.29%**
Total Protocols Submitted	150	181	228	245	249	265	290	372
Total Students and Faculty	19,144	19,068	20,290	20,884	21,944	24,013	23,031	24,339
Ratio Protocols/Faculty & Students	**0.78%**	**0.95%**	**1.12%**	**1.17%**	**1.13%**	**1.10%**	**1.26%**	**1.53%**

Institutional Emphasis on Research

A second variable that may be responsible for the increase in faculty submissions is the recent growing emphasis placed on research within the University. The hiring of President Carol Harter as President of UNLV in 1995 and the formulation and implementation of the UNLV Strategic Plan in 1996 with its greater emphasis on faculty research offers another change indicator that may have affected the submission rate of human subject protocols for research. The Strategic Plan and the University's Mission

Statement both speak to a greater importance of increasing research on campus. This factor could also account for the increase in protocol submissions.

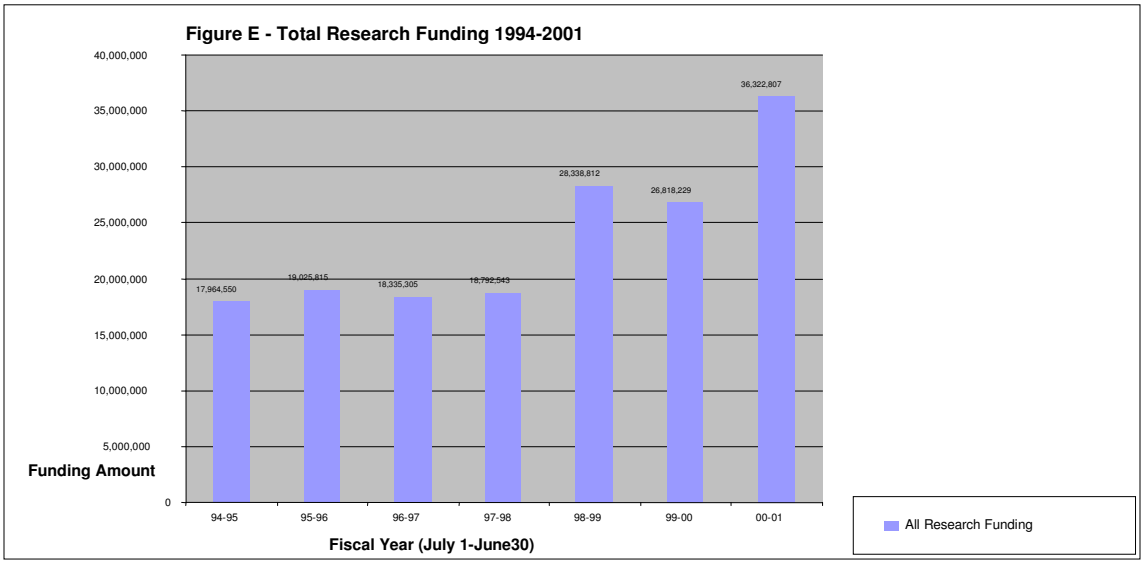
The dream of UNLV becoming known as a "premier research university" is clearly becoming a reality if one looks at the growth in funding received by UNLV faculty. One of the goals set forth in the Strategic Plan was for "research, creative activity and the development of community-based partnerships". The major increases in funding over the past five years indicate that researchers are searching all avenues of funding opportunities to assist them in their research and to meet the goals of the University's Strategic Plan. In 2000 the Carnegie category criteria were changed and UNLV was categorized as "Research/Doctoral – Extensive". There is only one category higher which requires that a university have a minimum of 50 graduate degree programs offered to its students. As part of Goal #4 of the University's strategic plan (Grow Selectively, Serve the Region, and Achieve Distinction), UNLV hopes to accomplish that higher goal by 2010 (http://www.unlv.edu/pubs/planning/goals.html).

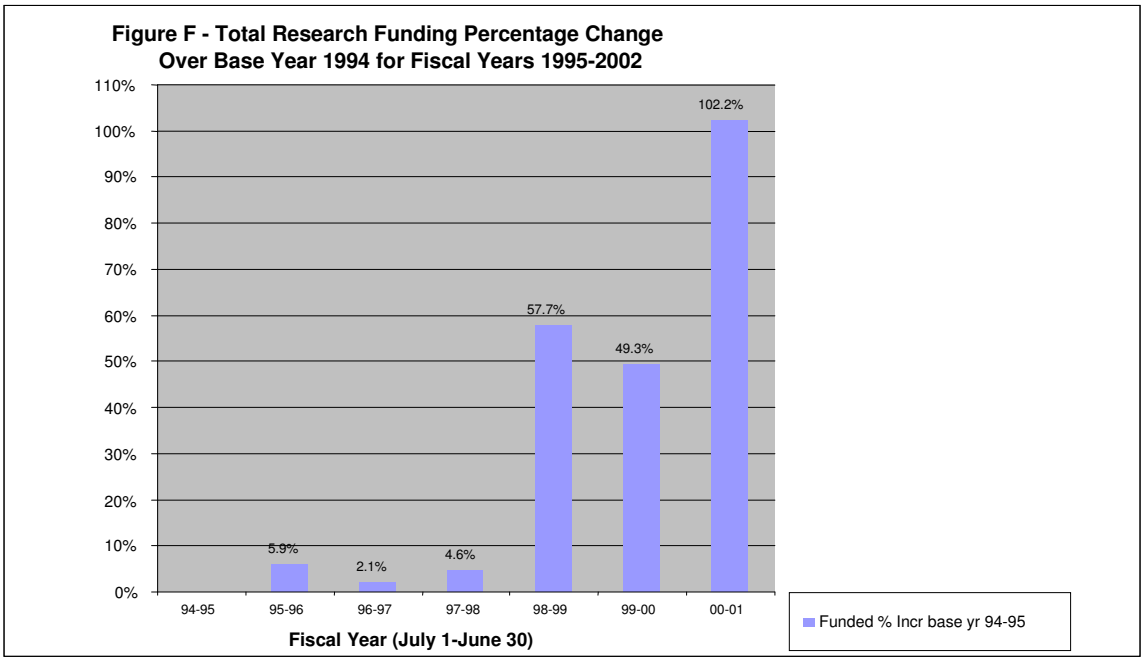
Without using regression or other more sophisticated analytical techniques, investigation of this factor can be at best suggestive. Here, an attempt is made to provide a rough indicator of the impact of this emphasis using data about the timing of the change in emphasis and the growth in research funding awards.

Funded awards for research, i.e., grants and contracts from private, local, state, and Federal government and financial aid to students, have grown at a phenomenal rate at UNLV over the past 10+ years. Figure E, "Total Research Funding 1994-2001", and Figure F, "Total Research Funding Percentage Change Over Base year 1994-1995", displays that growth. Information regarding funded awards was extracted from the

"Selected Institutional Characteristics" publications from Fall1994 to Fall 2001 which are compiled and published annually by the Office of Institutional Analysis and Planning, UNLV. Between 1995 and 1998, the funding level was only 5.9%, 2.1%, and 4.6% increases respectively over base year 1994-1995. Then in the 1998-02 fiscal years funding rose dramatically by 102.2% over base year 1990. It was during this period that the Colleges of Engineering and Urban Affairs received increased numbers of awards and the Office of Student Services received a greater funding amount for student financial aid. Evaluating the departments directly receiving research funding which involves human subjects would require a more in-depth investigation than time allowed for this study. Therefore, total research funding received was used for the basis of this evaluation.

Figures concerning growth in research awards suggest that this emphasis resulted in increased research activity.





In FY95, UNLV received $17,964,550 in research funding and financial aid. In FY01 UNLV received $36,322,807, an increase of 102.2% over FY95. Student Services financial aid from the U.S. Department of Education is included in this analysis only to demonstrate the amount of dollars UNLV receives in support of its students and research. The Colleges of Education, Engineering, Fine Arts, Health Sciences, and Sciences all showed major increases over the previous year as well as Student Services. The Harry Reid Center for Environmental Studies (HRC), a unique entity attached to UNLV under the Office of Research, received $7,553,603 funding in FY01 and has been a leader in the successful capturing of research dollars for UNLV over the past ten years. HRC's portion represents almost 21% of all funding received at UNLV for sponsored research projects and student services. Student Services received 25% of the total amount leaving researchers in all other departments and administrative offices receiving 54% of the funding through submission of research proposals.

VI. Conclusions

The following conclusions were drawn after examination and analysis of the statistical data presented above. In analyzing these data in terms of timeline of events presented, it appears that it may be too soon to say conclusively that the educational efforts of OPRS since July 2000 have made a significant impact on the number of protocols being submitted by University researchers. It is expected that there may be a lag in the time from creation of the new OPRS with more educational efforts being done and any kind of dramatic increase in protocol submissions resulting from that event. If academic years 2000-2002 are any indication of future growth in protocol submissions because of educational offerings by OPRS, then the University will see an even greater need for OPRS and its educational programs.

If one looks at the other causal variables studied, another pattern emerges with respect to the increases in protocol submissions from 1994-2002. The demographic growth of faculty and students has grown in a sometimes gradual and in some instances dramatic rate. By looking at the history of the University in terms of changes in leadership (Dr. Harter began her tenure at UNLV in 1995) and the implementation of the Strategic Plan (begun in 1996) which placed a higher level of weight on research by faculty for the purpose of UNLV being upgraded in the future to a Carnegie II research institution, it is apparent that this push by Administration also may have caused the gradual but sometimes great growth in the area of human subjects protocol submissions, especially by faculty. The research funding information presented adds further documentation of this push for “more research” by faculty with added impact on protocol submissions.

The "faculty vs. student" protocol submission ratios suggest that faculty are doing their "own" research and possibly excluding students in that regard. Students do not seem to be a part of the research scenario and appear to have become a secondary item of importance in the educational research process. There are several possible reasons why there has been a decrease in student protocol submissions. It may indicate that student researchers are (a) not being encouraged to do research involving human subjects for graduate work, (b) not being advised of their legal requirements to submit a protocol for class research, (c) possibly covered by a faculty blanket protocol for a "class" project, or (d) are not doing research that involves human subjects. It appears that much more educational outreach is needed in the area of educating students and encouraging protocol submissions. In placing a much higher emphasis on UNLV becoming a "premier urban research university," it places a greater burden on faculty and staff to increase their research output and at the same time continue the high quality of education of their students. Clearly, there is a lack that must be addressed in this area.

The human subjects' protection program at UNLV has grown and evolved through various offices and hands throughout the past 12-15 years. The importance of protecting human subjects and ensuring compliance with Federal regulations has not changed but its priority by the Federal government and on the University's list of "things to do" has increased greatly over the past few years and continues to increase as new research in DNA Recombatant, stem cell, biotechnical, sociological and other complex studies are being added daily to the research community's agenda. With the addition of a new cancer research institute and biotechnical research being conducted in the future, UNLV must be at the forefront of human subjects' protection education of its researchers.

The research goals in the UNLV Strategic Plan have served to push researchers to go beyond that of just a few years ago. UNLV is growing into a premier urban research institution and is taking the first step by increasing the educational level of UNLV researchers with regard to human subjects' research. As usual, more can and should be done in this area. OPRS has made a good start in the educational process but the work is just beginning.

Appendix A – Organizational Structure and Educational Efforts

YEAR	ORGANIZATIONAL STRUCTURE	EDUCATIONAL EFFORTS
1987	• Supervision of human subjects protection under Director of Grants & Research (G&R), Graduate College • Individual colleges and departments approve exempt protocols • Multiple Program Assurance (MPA) approved by DHHS for UCCSN and several other agencies which included UNLV	• Minimal educational effort • Regulation compliance by Director • Colleges and departments over-view for compliance with Federal and UNLV regulations
1989	• Office of Sponsored Programs (OSP) created • Director, G&R now Director, OSP • Hired Sponsored Programs Coordinator • Protocol reviews centralized under OSP with all protocols submitted for review/approval (exempt and expedited approved by OSP and full IRB review for others)	• Educational efforts increased with hiring of SPC • Researchers trained individually as protocols received • Occasional human subjects' protection presentations to graduate and undergraduate level classes in research methods • Time and budget constraints restricted educational efforts • Minimal "as requested" presentations to department/college faculty meetings
Nov. 1994	• SPC promoted to Assistant Director, OSP • New SPC hired in November 1994	• Continuation of above educational efforts • Time and budget constraints restricted additional educational efforts • New faculty orientation in Fall and Spring added
Sep. 1999	• New SPC hired in September 1999, • assumed program responsibilities until December 2000	• Continuation of above educational efforts • Time and budget constraints restricted additional educational efforts • No changes
Nov. 1999	• November 1999 DHHS representative visited UNLV and determined separate office for protection of research subjects required because of conflict of interest by OSP and human subjects program	
Jan. 2000 Jan. 2000,	• January 2000 to June 2000 a graduate student was hired to assume program responsibilities • Creation of Office for the Protection of Research Subjects (OPRS)	• Continuation of above educational efforts • Time and budget constraints restricted additional educational efforts

cont.	• Protocol reviews remained centralized under OPRS with all protocols submitted for review/approval. • All exempt protocols are now reviewed by IRB Chair (Social/Behavioral or Biomedical) • Expedited are reviewed by 3 members of either committee • Full IRB review for those requiring it	• No changes initially during this period
Jul. 2000 – Aug. 2002	• July 1st, Human Protections Administrator hired (full-time professional staff member) and a staff assistant hired also to assume program administration • Protocol reviews remained centralized under OPRS with all protocols submitted for review/approval • All exempt protocols are now reviewed by IRB Chair (Social/Behavioral or Biomedical) • Expedited are reviewed by 3 members of either committee • Full IRB review for those requiring it • June 2002, UNLV received approval of Federal-wide Assurance (FWA) from DHHS	• IRB membership evaluated and new members recruited • 489 faculty and students provided training thru faculty orientations and presentations to graduate and undergraduate research methods classes (2-3 per week) • 10/25/01 – one-day assurance compliance training by PRIM&R (IRB 101 on the Road) for 50 IRB members, faculty and student. • UNLV OPRS web site updated (http://www.unlv.edu/Research/OPRS/) • Investigator 101 CD-ROM available to faculty and students, individual use • NIH (Jul 2001) – web module training – "Human Participant Protections Education for Research Teams" Certification required with each protocol submitted. 100% all individuals submitting protocols have completed the assurance training since July 2001 • Faculty seminars presented at new faculty orientations Spring and Fall
Jan. 2003	• More comprehensive module identified as CITI will be utilized in place of the NIH certification	• Continuation of above

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