Refer to
Legislative Secretary

CARL T.C. GUTIERREZ
GOVERNOR OF GUAM

JAN 04 1999

The Honorable Antonio R. Unpingco
Speaker
Mina'Bente Kuåttro na Liheslaturan Guåhan
Twenty-Fourth Guam Legislature
Guam Legislature Temporary Building
155 Hesler Street
Hagåtña, Guam 96910

OFFICE OF THE LEGISLATIVE SECRETARY
Received by: [signature]
Time: 1:33pm
Date: 1-6-99

Dear Speaker Unpingco:

Enclosed please find Substitute Bill No. 347 (COR), "AN ACT TO *ADD* CHAPTER 24 TO DIVISION 3 OF TITLE 17 OF THE GUAM CODE ANNOTATED, RELATIVE TO DESIGNATING UOG'S COMMITTEE ON HUMAN SUBJECTS IN RESEARCH AS THE INSTITUTIONAL REVIEW BOARD FOR REVIEW AND APPROVAL OF RESEARCH CONDUCTED ON GUAM WITH REGARD TO HUMAN SUBJECTS", which was **vetoed** and subsequently overridden by i Liheslatura. This legislation is now designated as **Public Law No. 24-326.**

Very truly yours,

Carl T. C. Gutierrez
I Maga'lahen Guåhan
Governor of Guam

Attachment: copy attached for signed bill or overridden bill
original attached for vetoed bill

cc: The Honorable Joanne M. S. Brown
Legislative Secretary

00003

Office of the Speaker
ANTONIO R. UNPINGCO
Date: 1/6/99
Time: 10:49am
Rec'd by: [signature]
Print Name: Laurie

MINA'BENTE KUATTRO NA LIHESLATURAN GUAHAN
1998 (SECOND) Regular Session

CERTIFICATION OF PASSAGE OF AN ACT TO *I MAGA'LAHEN GUAHAN*

This is to certify that Substitute Bill No. 347 (COR), "AN ACT TO *ADD* CHAPTER 24 TO DIVISION 3 OF TITLE 17 OF THE GUAM CODE ANNOTATED, RELATIVE TO DESIGNATING UOG'S COMMITTEE ON HUMAN SUBJECTS IN RESEARCH AS THE INSTITUTIONAL REVIEW BOARD FOR REVIEW AND APPROVAL OF RESEARCH CONDUCTED ON GUAM WITH REGARD TO HUMAN SUBJECTS," returned without approval of *I Maga'lahen Guahan*, was reconsidered by *I Liheslaturan Guahan* and after such consideration, did agree, on the 30th day of December, 1998, to pass said bill notwithstanding the veto of *I Maga'lahen Guahan* by a vote of fourteen (14) members.

ANTONIO R. UNPINGCO
Speaker

Attested:

JOANNE M.S. BROWN
Senator and Legislative Secretary

This Act was received by *I Maga'lahen Guahan* this 31ST day of December, 1998, at 3:10 o'clock P.M.

Assistant Staff Officer
Maga'lahi's Office

Public Law No. 24-326

MINA' BENTE KUATTRO NA LIHESLATURAN GUAHAN
1997 (First) Regular Session

Bill No. 347 (COR)
As substituted by the Committee
on Education and as amended
on the Floor.

Introduced by:

L. A. Leon Guerrero
W. B.S.M. Flores
T. C. Ada
F. B. Aguon, Jr.
A. C. Blaz
J. M.S. Brown
Felix P. Camacho
Francisco P. Camacho
M. C. Charfauros
E. J. Cruz
Mark Forbes
L. F. Kasperbauer
A. C. Lamorena, V
C. A. Leon Guerrero
V. C. Pangelinan
J. C. Salas
A. L.G. Santos
F. E. Santos
A. R. Unpingco
J. T. Won Pat

AN ACT TO *ADD* CHAPTER 24 TO DIVISION 3 OF TITLE 17 OF THE GUAM CODE ANNOTATED, RELATIVE TO DESIGNATING UOG'S COMMITTEE ON HUMAN SUBJECTS IN RESEARCH AS THE INSTITUTIONAL REVIEW BOARD FOR REVIEW AND APPROVAL OF RESEARCH CONDUCTED ON GUAM WITH REGARD TO HUMAN SUBJECTS.

BE IT ENACTED BY THE PEOPLE OF GUAM:

Section 1. Legislative Findings. *I Liheslaturan Guahan* finds that research studies involving human subjects are conducted on Guam, and realizes a need to protect the rights of persons participating in human research projects through a review of research proposals, plans, procedures and protocols. It further finds that designation of the University of Guam's ("UOG's") Committee on Human Subjects in Research as the Institutional Review Board ("IRB") for researchers and collaborators at University of Guam and for researchers who are *not* under other IRB's is the appropriate body to review proposals, plans, procedures and protocol for research involving human subjects and to approve or disapprove the same.

Furthermore, *I Liheslaturan Guahan* finds that human research conducted on Guam do *not* always acquire informed consent from persons participating in the programs, and that there is a need to regulate and mandate informed consents to ensure that those persons participating are adequately informed.

The Review Board will be under the auspices of UOG as it has been identified as the suitable entity under the direction of the Graduate School and Research Department.

Section 2. Chapter 24 is hereby *added* to Division 3 of Title 17 of the Guam Code Annotated to read as follows:

"CHAPTER 24.

Section 24101. Definitions. As used in this Chapter:

(a) *'Board'* means the Guam Research Review Board.

(b) *'Investigator'* means any individual, public or private entity, or agency engaged in or purposing to engage in research subject to regulation.

(c) *'Legally'* authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) *'Research'* as defined in the Federal Register, §102 Definitions.

(e) *'Research'* subject to regulation means research involving human subjects.

(f) *'Human subjects'* means a living individual about whom an investigator conducting research obtains:

(1) **Data Through Intervention or Interaction with the Individual.** Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

(2) **Identifiable Private Information.** Private information may include information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will *not* be made public (for

example, medical records). Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects.

(g) *'Minimal risk'* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

Section 24102. Board; Terms; Appointment; Continuance; Removal. Members of the Board shall be consistent with the University of Guam's Committee on Human Subjects and Research which is: three (3) or four (4) professional research proficient experts from the University of Guam; at least one (1) Guam community representative; at least one (1) local religious leader; and at least one (1) licensed practicing local medical doctor.

Section 24103. Purpose. The purpose of the Board is to review, approve, require modifications to secure approval or disapprove all research subject to regulation.

Section 24104. Powers. The Board shall have and exercise each and all of the following powers:

(a) review and have authority to approve, require modifications to secure approval or disapprove all research activities covered by the rules and regulations;

(b) require documentation of informed consent of all human subjects participating in the research subject to regulation. At the Board's discretion, require additional information be given

to the subjects which would add to the protection of the rights and welfare of the subjects;

(c) notify the investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure approval of the research activity. If the Board decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing;

(d) conduct continuing review of research subject to regulation at intervals appropriate to the degree of risk, but not less than once per year and shall have authority to observe or have a third party observe and consent to the process and the research; *and*

(e) to disapprove research subject to regulation which had been previously approved.

Section 24105. Duties of Investigators. The proposals, plans, procedures and protocols for all proposed research subject to regulation shall be submitted to the Board for review, approval, modification or disapproval. No research subject to regulation shall be conducted without Board approval. The plans, procedures and protocols for all research subject to regulation which is being conducted at the time of the enactment of this legislation shall be submitted to the Board for review, approval, modification or disapproval within thirty (30) days of this bill becoming law. Research

subject to regulation which is being conducted at the time of the enactment of this legislation may continue pending Board action.

Section 24106. General Requirements for Informed Consent. No investigator may involve a human being in research subject to regulation *unless* the investigator has obtained the legally effective informed consent of the subject, or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate, and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. Unless otherwise provided by law or regulation, no informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the research sponsor, if different, or their agents from liability for negligence.

(a) Basic Elements of Informed Consent. Except as provided in Paragraphs (c) or (d) of this Section, in seeking informed consent the following information shall be provided to each human subject or the subject's legally authorized representative:

(1) a statement that the study involves research, an explanation of the purpose of the research and the expected

duration of the subject's participation, description of the procedures to be followed and identification of any procedures which are experimental;

(2) a description of any reasonably foreseeable risk or discomforts to the subject;

(3) a description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) a disclosure of appropriate alternative procedures or courses or treatment, if any, that might be advantageous to the subject;

(5) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs, and, if so, what it consists of or whether further information may be obtained;

(7) an explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject; *and*

(8) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the

subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional Elements of Informed Consent.

When appropriate, the Board may require that one (1) or more of the following elements of information shall also be provided to each subject:

(1) a statement that the particular treatment or procedure may involve risks to the subject, or to the embryo or fetus, if the subject is or may become pregnant, which are currently unforeseeable;

(2) anticipated circumstances under which the subject's participation may be terminated by an investigator without regard to the subject's consent;

(3) any additional cost to the subject that may result from participation in the research;

(4) the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; *and*

(6) the approximate number of subjects involved in the study.

(c) The Board may approve a consent procedure which does *not* include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent; provided, that the Board finds and documents that:

(1) the research or demonstration project is to be conducted by, or subject to, the approval of Federal, state, territorial or local government officials, and is designed to study, evaluate or otherwise examine: (i) public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes and/or alternatives to those programs or procedures; *or* (iv) possible changes in methods or levels of payments for benefits or services under those programs; *and*

(2) the research could *not* practically be carried out without the waiver or alteration.

(d) The Board may approve a consent procedure which does *not* include, or which alters, some or all of the elements of informed consent set forth in this Section, or waives the requirements to obtain informed consent; provided, that the Board finds and documents that:

(1) the research involves no more than minimal risk to the subject;

(2) the waiver or alteration will *not* adversely affect the rights and welfare of the subject;

(3) the research could *not* practically be carried out without the waiver or alteration; *and*

(4) whenever appropriate, the subjects will be provided with additional and pertinent information after participation.

(e) The informed consent requirements are *not* intended to preempt any applicable Federal, state or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this Section is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state, or territorial law.

Section 24107. Criteria for Board Approval of Research.

In order to approve research subject to regulation, the Board shall determine that all the following requirements are satisfied:

(a) Risks to subject are minimized: (i) by using procedures which are consistent with sound research design and which do *not* unnecessarily expose subject's to risk; and (ii) whenever appropriate by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(b) Risks to subject are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the Board should consider only

those risks and benefits that may result from the research, as distinguished from risks and benefits of therapies subject would receive even if *not* participating in the research. The Board should *not* consider possible long range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(c) Selection of the subjects is equitable. In making this assessment the Board should take into account the purposes of the research and the setting in which the research would be conducted and should be particularly cognizant of the special problems that research involving vulnerable populations, such as children, prisoners, pregnant woman, persons with disabilities, the elderly, or economically or educationally disadvantaged persons.

(d) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Board regulation.

(e) Informed consent will be appropriately documented, in accordance with, and to the extent required by Board regulation.

(f) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(g) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, the elderly, prisoners, pregnant women, mentally disabled persons or economically or educationally disadvantaged persons, additional safeguards have been included in the research plans, procedures or protocols to protect the rights and welfare of these subjects.

(h) Progress reports or thesis shall be made available to subjects participating in the research as appropriate.

Section 24108. Grievance Procedure. If application for approval is denied for a research proposal, investigators may appeal to the Dean of the Graduate School and Research. The Dean will appoint an ad hoc committee for a second, independent review of the research project. The findings of the ad hoc committee are to be presented to the Committee on Human Subjects in Research no later than ninety (90) days after receipt of grievance from the investigator, to determine the final decision to approve or not to approve a research project.

Section 24109. Fines and Penalties. Upon determination of the Review Board through the approved rules and regulations, any investigator, research sponsor or their agents, which conducts research subject to regulation in violation of this Chapter shall be subject to a fine of One Thousand Dollars ($1,000.00) per each violation, and shall be

prohibited from continuing and conducting human research studies for not less than two (2) years.

The Dean of the Graduate School and Research shall refer any cases determined by the Review Board as a valid violation to the Attorney General's Office for investigation and prosecution.

Section 24110. Appropriation: Authorization. There is hereby appropriated from the General Fund a total of Forty Thousand Dollars ($40,000.00) for the purpose of hiring one (1) clerical staff and other accommodations necessary to assist with the function of processing applications. This appropriation shall continue until expended for the operations and purposes specified herein."

PL24-326

TWENTY-FOURTH GUAM LEGISLATURE
COMMITTEE ON EDUCATION

215-A Chalan Santa Papa, Suite 106-F
Ada's Professional & Commercial Center
Agaña, Guam 96910

Telephone (671) **475-KIDS**
Fax (671) **475-2000**
e-mail **lk4kids@ite.net**

October 22, 1998

The Honorable Antonio R. Unpingco
Speaker, 24th Guam Legislature
Hagåtña, Guam

via: Committee on Rules

Dear Mr. Speaker:

The Committee on Education to which was referred **Bill No. 347 (COR):** "AN ACT TO ADD CHAPTER 24, DIVISION 3, 17 GCA TO DESIGNATE THE UNIVERSITY OF GUAM'S COMMITTEE ON HUMAN SUBJECTS IN RESEARCH AS THE INSTITUTIONAL REVIEW BOARD FOR REVIEW AND APPROVAL OF RESEARCH CONDUCTED ON GUAM WITH REGARD TO HUMAN SUBJECTS," herein reports back with the recommendation **TO DO PASS Substitute Bill No. 347.**

Votes of the committee members are as follows:

7 To Pass

_____Not To Pass

_____To The Inactive File

_____Abstained

Sincerely,

LAWRENCE F. KASPERBAUER

Attachments

TWENTY-FOURTH GUAM LEGISLATURE
COMMITTEE ON EDUCATION

215-A Chalan San Pedro Papa, Suite 106-F
Ada's Professional & Commercial Center
Agaña, Guam 96910

Telephone (671) **475-KIDS**
Fax (671) **475-2000**
e-mail **lk4kids@ite.net**

October 22, 1998

TO: **All Members**
Committee on Education

FROM: **Chairman**

SUBJ: **Voting Sheet**

Transmitted herewith is the voting sheet and committee report for **Substitute Bill No. 347 (COR):** "AN ACT TO ADD CHAPTER 24, DIVISION 3, 17 GCA TO DESIGNATE THE UNIVERSITY OF GUAM'S COMMITTEE ON HUMAN SUBJECTS IN RESEARCH AS THE INSTITUTIONAL REVIEW BOARD FOR REVIEW AND APPROVAL OF RESEARCH CONDUCTED ON GUAM WITH REGARD TO HUMAN SUBJECTS."
Your attention to this matter is greatly appreciated.

Sincerely,

LAWRENCE F. KASPERBAUER

Attachments

COMMITTEE ON EDUCATION
TWENTY-FOURTH GUAM LEGISLATURE
155 Hesler Street, Agana, Guam 96910

Chairman: Senator Lawrence F. Kasperbauer Vice Chairman: Senator John C. Salas
Ex-Officio Member: Speaker Antonio R. Unpingco

VOTING SHEET ON:

Substitute Bill No. 347 (COR): "AN ACT TO ADD CHAPTER 24, DIVISION 3, 17 GCA TO DESIGNATE THE UNIVERSITY OF GUAM'S COMMITTEE ON HUMAN SUBJECTS IN RESEARCH AS THE INSTITUTIONAL REVIEW BOARD FOR REVIEW AND APPROVAL OF RESEARCH CONDUCTED ON GUAM WITH REGARD TO HUMAN SUBJECTS."

COMMITTEE MEMBERS	INITIAL	TO PASS	NOT TO PASS	ABSTAIN	TO PLACE IN INACTIVE FILE
Sen. Lawrence F. Kasperbauer *Chairman*		X			
Sen. John C. Salas *Vice-Chairman*		✓			
Spkr. Antonio R. Unpingco *Ex-Officio Member*					
Sen. Thomas C. Ada *Member*		✓			
Sen. Frank B. Aguon, Jr. *Member*		✓			
Sen. Anthony C. Blaz *Member*					
Sen. Joanne M.S. Brown *Member*					
Sen. Felix P. Camacho *Member*					
Sen. Francisco P. Camacho *Member*					
Sen. Edwardo J. Cruz *Member*					
Sen. Mark Forbes *Member*		✓			
Sen. Angel L.G. Santos *Member*					
Sen. Judith Won Pat *Member*		✓			

COMMITTEE REPORT
COMMITTEE ON EDUCATION
May 5, 1998

Bill No. 347: AN ACT TO CREATE A REVIEW BOARD OF REVIEW AND APPROVAL OF RESEARCH CONDUCTED ON GUAM WITH REGARD TO HUMAN SUBJECTS.

Senators present: Senator Larry Kasperbaur, Chairperson, Senator Lou Leon Guerrero, Senator Mark Charfauros and Senator Frank Camacho.

Those present to testify were: Dr. Jose T. Nededog, President, University of Guam, Dr. Joyce Camacho, Dean of Graduate School and Research, University of Guam, Dr. Kyle Smith, Professor of Psychology, University of Guam, Dr. Randall L. Workman, Professor of Sociology, University of Guam, Gregoria Smith, Psychometrist, UOG/UCSD Research Project, Mr. Ray Adonay, Dr. Bert Weiderholt, Physician/Neurologist, University of California-San Diego and Debbie Quinata.

Those not present, but submitted written testimony were: Dr. John Steele, Dr. Marcus Tye, Asst. Professor, Psychology, University of Guam, Dr. Richard Colfax, Management & Marketing Chairperson, University of Guam, Dr. Seyda Turk Smith, Associate Professor, Psychology, University of Guam, Dr. Pamina J. Hofer, Clinical Neurolopsychologist and Guam Lytico and Bodig Association.

Overview of Bill

Senator Lou Leon Guerrero shared with the Committee members and the audience an overview of Bill 347.

Bill 347 was drafted as a result of a public hearing conducted during the 23rd Guam Legislature when Senator Lou Leon Guerrero was Chairperson of Health, Welfare & Senior Citizens to discuss various

research done on Guam. There was a public outcry on how we protect human subjects for research. The University of Guam has a review board, as well as the Guam Memorial Hospital. However, Bill 347 will set forth rules and regulations to assure that people are protected with informed consent. All research studies and methodologies must go through a review process.

Oral Testimonies

Dr. Jose Nededog, President, University of Guam presented his oral testimony in support of Bill 347. He indicated that this bill can act as an umbrella for various research done on Guam. His concern was that the present staff is overtasked and the bill should be modified to include support - a clerk and supporting equipment.

Dr. Joyce Camacho, Acting Dean for Graduate School and Research submitted oral testimony to support Bill 347. Her concerns include (1) duplication of existing review; (2) the role of University of Guam in research; (3) delays in conducting research; and (4) composition of Committee members as stated in the proposed legislation.

Dr. Camacho gave some background information on the existing research board: The Research Council is comprised of the Dean of Graduate School and Research, Dean of Learning Resources, Directors of Research Institute, Associate Dean of Agriculture Experiment Studies and elected faculty from the five (5) academic colleges with an ex-officio representative to the Council of Undergraduate Research.

The Council meets bimonthly to discuss relevant research issues. Their tasks include development, review and enforcement of research policy at the University of Guam. One of the standing committees of the Research Council is the Committee on Human Subjects in Research. They are tasked with reviewing and approving or disapproving of research proposals that involve human subjects. They have existed since 1982 and serve Guam by providing

protection to human subjects in accordance with federal/local regulations in research.

Suggested changes.

Change the words "Creation of Guam Research Review Board" and replace with "The designation of the University of Guam's Committee on Human Subjects in Research as the Institutional Review Board or (IRB) for researchers and collaborators at the University and for researchers who are not under other IRBs." Wherever the bill states "Guam Research Review Board" it should be replaced with "UOG's Committee on Human Subjects in Research".

As with Dr. Nededog comments, clerical staff need to be assigned to ensure that the functions of the Committee are carried out.

Dr. Randall Workman, Professor of Sociology and Community Development at the University of Guam testified in support of the intent of Bill 347. His written testimony outlined his concerns which includes the importance of informed consent and assessment of risks and benefits. Further, the bill, as currently written, establishes unnecessary additional island wide IRB.

Dr. Kyle Smith teaches psychology and research methods at the University of Guam and fully supports the call for all research conducted on Guam to undergo review. The bill, as in its existing form may produce some unnecessary affects on the training available for standards at the University of Guam and creates redundant delays. He supports the option to modify the bill to accommodate student and research projects. Dr.Smith believes that it was not the intent of the author to impede research projects. He will fully support the bill with modifications.

Mr. Roy Adonay testified in support of Bill 347. Mr. Adonay expressed the need to review the are of fines and penalties and needs to be expanded. There is no indication as to who will monitor and

fine and who will collect. The University of Guam will not have the power or authority to police all research.

Ms. Gregoria Smith testified in favor of Bill 347. She also submitted written testimony that states obtaining consents from participants are necessary in the practice of research to protect the rights of those who participates. Researchers must be trained; research, especially scientific research, requires special training.

Ms. Debbie Quinata, a member of OPIR, Chamorro Nation, ancestral/original landowners. Ms. Quinata is opposed to Bill 347. Guam already has an IRB for grant applicant that review standards at the Guam Memorial Hospital. This bill will create more loopholes. Ms. Quinata also stated that all off-island researchers should share in the results of the national research and charge fees. Mechanisms should be in place to ask for accountability - what are they doing for our island and educating our students.

Dr. Bert Weiderholt, physician/neurologist and professor of neuroscience at the University of California, San Diego. NIA (National Institutes of Aging) funded program project for 5 years to study disease on Guam. Dr. Wiederholt is in full support of Bill 347 and further supports Drs. Nededog and Camacho, Workman and Smith. He has conducted research in various states and it is very important to submit research project for local review, although not federally required. Dr. Weiderholt and the project he is now involved in on Guam, had no hesitation in submitting application for research to the University of Guam and the Guam Memorial Hospital - both were approved.

Senator Charfauros supports research and Bill 347. He suggested various amendments to the bill: need rules/regulations, more liability for researchers, require license to practice, progress reports made available to public, increase fine to $10,000 for violation, commercial profits need to be shared with research subjects and no exploitation of research subjects.

Senator Kasperbauer shared his concerns with exploited research subjects and need protection.

Final Summary

As author of Bill 347, Senator Lou Leon Guerrero gave final remarks. She welcomed any amendments to assure the intent of legislation is achieved - to protect human subjects. Although there are IRBs at Guam Memorial Hospital and the University of Guam, there is research being conducted that are not associated with these institutions. Therefore, we are not assured that the research subjects are protected. When discussing the bill with the representatives at the University of Guam, there was discussions to expand the existing Human Research Committee. The community needs to be part of the research conducted.

Recommendation

It is the recommendation of the Committee on Education **TO DO PASS AS SUBSTITUTED BY THE AUTHOR BILL NO. 347, AN ACT TO ADD CHAPTER 24, DIVISION 3, 17 GCA TO DESIGNATE THE UNIVERSITY OF GUAM'S COMMITTEE ON HUMAN SUBJECTS IN RESEARCH AS THE INSTITUTIONAL REVIEW BOARD FOR REVIEW AND APPROVAL**

24th Guam Legislature
Committee on Rules, Government Reform and Federal Affairs
Senator Mark Forbes, Chairman

APR 0 8 1998

RECEIVED
APR 0 9 1998

MEMORANDUM

TO: Chairman
Committee on Education

FROM: Chairman
Committee on Rules, Government Reform and Federal Affairs

SUBJECT: Referral - Bill No. 347

The above Bill is referred to your Committee as the principal committee. It is recommended you schedule a public hearing at your earliest convenience.

Thank you for your attention to this matter.

MARK FORBES

Attachment

155 Hesler Place • Agana, Guam • 96910 • Telephone Numbers 472-3512, 472-3407/8

TWENTY-FOURTH GUAM LEGISLATURE
1997 (First) Regular Session

Bill No. 347
As substituted by the Author
Introduced by: L. Leon Guerrero
W.Flores
T.Ada

AN ACT TO ADD CHAPTER 24, DIVISION 3, 17 GCA TO CREATE A REVIEW BOARD FOR REVIEW AND APPROVAL OF RESEARCH CONDUCTED ON GUAM WITH REGARD TO HUMAN SUBJECTS.

BE IT ENACTED ON BY THE PEOPLE OF THE TERRITORY OF GUAM:

Section 1. Legislative Findings. The legislature finds that research studies involving human subjects are conducted on Guam and realizes a need to protect the rights of persons participating in human research projects through a review of research proposals, plans, procedures and protocols. It further finds that the creation of a review board is the appropriate body to review proposals, plans, procedures and protocol for research involving human subjects and to approve or disapprove the same.

Furthermore, the legislature finds that human research conducted on Guam do not always acquire informed consent from persons participating in the programs and that there is a need to regulate and mandate informed consents to ensure that those persons participating are adequately informed.

The review board will be under the auspices of the University of Guam as it has been identified as the suitable entity under the direction of the Graduate School and Research Department.

Section 2. Division 3 of Title 17 GCA, is hereby amended to add Chapter 24 to read as follows:

"Chapter 24

§24101. Definitions. As used in this chapter:

(a) *Board* means the Guam Research Review Board;

(b) *Investigator* means any individual, public or private entity or agency engaged in or purposing to engage in research subject to regulation;

(c) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to the understanding of a particular condition or generalized knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may fall under this definition of research. Not included in this definition are:

(1) Opinion polls or other similar investigations of the human subjects' opinions or beliefs;

(2) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies or (ii) research on the effectiveness or the comparison among instructional techniques, curricula or classroom management methods;

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: ;(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifier's linked to the subjects; and (ii) any disclosure of the human subject's responses outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability or reputation;

(4) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures or observation or public behavior that is not exempted under paragraph (d)(2) of this section, if: (i)

2/3

Boards ensure that the appropriate legal standards, controls, and laws as well as organizational and ethical guidelines are followed. Among these are (this list is not exclusive or exhaustive):

- UOG Guidelines and Procedures for the "Institutional Review Assuring Human Rights of Subjects" by the Committee on Human Subjects in Research (CHSR)
- UOG Guidelines regarding the "Ethical Principles and Guidelines for the Protection of Human Subjects of Research"
- GMH Institutional Review Board Policies and Procedures (4/13/95)
- Applicable Federal Regulations (1974 and later) as issued by the U.S. Department of Health, Education, and Welfare
- Applicable regulations of the Office for Protection from Research Risks (OPRR), National Institute of Health, Department of Health and Human Services
- Applicable regulations of the US Food and Drug Administration (FDA)
- Comply with the "Belmont Report" as adopted by the National Commission for the Protection of Human Subjects
- Applicable codes of conduct of social and behavioral research as adopted by the American Psychological Association (APA) since 1973
- Health Research Extension Act of 1985
- Federal Public Law 99-158

Therefore there is NO NEED TO DUPLICATE THESE EXISTING REVIEW BOARDS BY ESTABLISHING A NEW REVIEW BOARD that has no guarantee of providing equal quality reviews or protection to the People of Guam. The existing UOG Committee for Human Subject in Research (CHSR) and the Guam Memorial Hospital Institutional Review Board (IRB) for Research provide this protection to the People of Guam, and will continue to provide this protection to the People of Guam if permitted to continue serving the People of Guam as they presently do. This points in the direction of the need for a major revision of Bill #347 to identify the existing UOG Committee for Human Subject in Research (CHSR) with the existing UOG policies and procedures as the designated Review Board for all research related to human subjects on Guam.

Roles of UOG and GMH

A further redundancy is evident as the Bill identifies that the proposed Review Board will involve the University of Guam under the control and guidance of the UOG President. This is already in place. The proposed Bill #347 is a redundancy of the existing official UOG research review control body: the Committee for Human Subject in Research (CHSR) which serves the community as an official appointed standing committee at UOG. RATHER, I believe BILL #347 SHOULD IDENTIFY THE UOG COMMITTEE FOR HUMAN SUBJECT IN RESEARCH (CHSR) AS THE DESIGNATED REVIEW BOARD for all research projects related to human subjects ON GUAM.

Members of these Review Boards

The proposed Bill #347 identifies review board members to create a new review body that would again be nearly identical to representative membership of the Committee for Human Subject in Research (CHSR) which exists at UOG. The UOG CHSR has continuously consisted of (but not been limited to):

- 3 or 4 professional research proficient experts from UOG
- at least 1 Guam Community Representative
- at least 1 local Religious leader
- at least 1 licensed practicing local Medical Doctor

AND has always accessed other community and professional advisors or resources where appropriate when reviewing research proposals.

Moreover the Guam Memorial Hospital Institutional Review Board (IRB) for Research is also composed of an equally representative body of professional researchers, educators, and local leaders. In accordance with the Institutional Review Board Policies and Procedures (4/13/95), the Guam Memorial Hospital IRB is composed of (but not limited to):

1/3

University of Guam
Unibetsedåt Guahan

College of Business and Public Administration
UOG Station, Mangilao, GU 96923

May 4, 1998

To: Senator Larry Kasperbauer, Ph.D.
Chair of the Committee on Education

From: Richard Colfax, Ph.D. Mgmt. & Mktg. Dept. Chair

RE: Bill #347: Relative to Creating a Guam Research Review Board

Senator Kasperbauer:

Hafa Adai.
Dr. Joyce Camacho, Acting Dean of the UOG Graduate School & Research, provided me with a copy of the draft of Bill #347. I have read it very carefully and have reviewed the UOG provided documents and directives related to research conducted with regard to human subjects. I am an active member of the University of Guam's Committee on Human Subjects in Research (CHSR) and have been since my appointment in 1995. Further, I have been a co-representative of UOG on the Guam Memorial Hospital (GMH) Institutional Review Board (IRB) for Research for 2 years.

Since I am unable due to scheduled classes at UOG to attend the Public Hearing on Bill #347 on May 5, I would like to have the following included in the documents and testimonies that your Committee considers as it makes deliberations about this Bill.

Duplication of Existing Review Boards

In reading the draft of Bill #347, the existence of the established research review and control bodies that have been serving the People of Guam for many years seem to have been unrecognized or blatantly ignored. I believe that the Legislature and your Committee are aware of the existence of the UOG Committee on Human Subjects in Research (CHSR) and the Guam Memorial Hospital Institutional Review Board (IRB) for Research. Both of these entities presently exist and actively serve the People of Guam by providing the exact same protections to the people of Guam that Bill #347 implies are not being given at this time.

I BELIEVE THAT BILL #347 IS IMPORTANT BUT AS WORDED WILL INTERFER WITH, COMPLICATE AND CREATE PROBLEMS IN THE NEEDED RESEARCH THAT INVOLVES GUAM AND THE PEOPLE OF GUAM. I agree that it is important to address research issues that might not be covered under existing UOG, GMH or DOE policies. However, Bill #347, as worded, appears to go beyond the intent of the federal guides for research related to human subjects. The People of Guam and researchers who conduct research related to humans on Guam are already protected by excellent existing Review Boards and policies. These existing Review Boards professionally review and monitor most proposed, new and ongoing research activities that falls under their jurisdiction related to humans here on Guam. As stated above, these Review Boards are the UOG Committee on Human Subjects in Research (CHSR) and the Guam Memorial Hospital Institutional Review Board (IRB) for Research.

The People of Guam are adequately protected in accordance with the U.S. federal and local regulations related to human subjects in research by the UOG Committee on Human Subjects in Research (CHSR) and the Guam Memorial Hospital Institutional Review Board (IRB) for Research. These existing active Review

the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal or local statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter;

(5) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is reported by the investigator in such a manner that subjects cannot be identified, directly or through identifiers that link through the subject;

(6) Research and demonstration projects which are designed to study, evaluate, or otherwise examine: (i) public benefits or service programs; (ii) procedures for obtaining benefits or services under those programs; (ii) possible changes and/or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payments for benefits or services under those programs; and

(7) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a good is consumed that contains a food ingredient at or below the level an for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety Inspection Service of the United States Department of Agriculture.

(e) *Research subject to regulation* means research involving human subjects.

(f) *Human subjects* means a living individual about whom an investigator conducting research obtains

(1) Data through intervention or interaction with the individual. Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

(2) Identifiable private information. Private information may include information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical records). Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects.

(g) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not grater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

§24102. Board; Terms; Appointment; Continuance; Removal. There is created a seven (7) member "Guam Research Review Board" under the direction of the Office of the Graduate School and Research at the University of Guam. Members of the Board shall be comprised of representatives of the following: one (1) member from the Guam Memorial Hospital Institutional Review Board; one (1) member from the University of Guam Institutional Review Board; (1) member of the clergy; the Director of the Department of Public Health and Social Services or his/her designee; two (2) community representatives recommended by the Mayor's Council; and an attorney licensed to practice in the Territory of Guam. Members of the Board shall be appointed by the President of the University of Guam. The Board shall be appointed for a three (3) year term. The President of the University of Guam may remove any member from the Board for the neglect of any duty required by law, for incompetence, for improper and unprofessional conduct or for violation of Board rules and regulations. Four (4) members shall constitute a quorum of the Board for the transaction of business. The Board shall adopt rules and regulations in accordance with existing federal law, if applicable and the Administrative Adjudication Act, governing the conduct of its affairs and exercise of its powers within ninety (90) days of enactment of this law.

§24103. Purpose. The purpose of the Board is to review, approve, require modifications to secure approval or disapprove all research subject to regulation.

§24104. Powers. The Board shall have and exercise each and all of the following powers:

(a) Review and have authority to approve, require modifications to secure approval or disapprove all research activities covered by the rules and regulations.

(b) Require documentation of informed consent of all human subjects participating in the research subject to regulation. At the Board's discretion, require additional information be given to the subjects which would add to the protection of the rights and welfare of the subjects;

(c) Notify the investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure approval of the research activity. If the Board decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing;

(d) Conduct continuing review of research subject to regulation at intervals appropriate to the degree of risk, but not less than once per year and shall have authority to observe or have a third party observe and consent to the process and the research; and

(e) To disapprove research subject to regulation which had been previously approved.

§24105. Duties of Investigators. The proposals, plans, procedures and protocols for all proposed research subject to regulation shall be submitted to the Board for review, approval, modification, or disapproval. No research subject to regulation shall be conducted without Board approval. The plans, procedures and protocols for all research subject to regulation which is being conducted at the time of the enactment of this legislation shall be submitted to the Board for review, approval, modification or disapproval within thirty (30) days of this bill becoming law. Research subject to regulation which is being conducted at the time of the enactment of this legislation may continue pending Board action.

§24106. General Requirements for Informed Consent. No investigator may involve a human being in research subject to

regulation unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. Unless otherwise provided by law or regulation, no informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the research sponsor, if different, or their agents from liability for negligence;

(a) Basic elements of Informed Consent. Except as provided in paragraphs (c) or (d) of this section, in seeking informed consent the following information shall be provided to each human subject or the subject's legally authorized representative:

(1) A statement that the study involves research, an explanation of the purpose of the research and the expected duration of the subject's participation, description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risk or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses or treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what it consist of or whether further information my be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional Elements of Informed Consent. When appropriate, the Board may require that one (1) or more of the following elements of information shall also be provided to each subject;

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by an investigator without regard to the subject's consent;

(3) Any additional cost to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) The Board may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided that the Board finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of federal, state, territorial or local government officials and is designed to study, evaluate or otherwise examine: (i) public

benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes and/or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payments for benefits or services under those programs; and

(2) The research could not practically be carried out without the waiver or alteration.

(d) The Board may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided that the Board finds and documents that:

(1) The research involves no more than minimal risk to the subject;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subject;

(3) The research could not practically be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional and pertinent information after participation.

(e) The informed consent requirements are not intended to preempt any applicable federal, state or local laws which require additional information to be disclosed in order for informed consent to be legally effective; and

(f) Nothing in this section is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or territorial law.

§24107. Criteria for Board Approval of Research. In order to approve research subject to regulation, the Board shall determine that all the following requirements are satisfied:

(a) Risks to subject are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subject's to risk; and (ii) whenever appropriate by using procedures already being performed on the subjects for diagnostic or treatment purposes;

(b) Risks to subject are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and

benefits, the Board should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subject would receive even if not participating in the research). The Board should not consider possible long range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility;

(c) Selection of the subjects is equitable. In making this assessment the Board should take into account the purposes of the research and the setting in which the research would be conducted and should be particularly cognizant of the special problems that research involving vulnerable populations such as children, prisoners, pregnant woman, persons with disabilities, the elderly, or economically or educationally disadvantaged persons;

(d) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Board regulation.

(e) Informed consent will be appropriately documented, in accordance with, and to the extent required by Board regulation.

(f) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects; and

(g) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

When some or all of the subject are likely to be vulnerable to coercion or undue influence, such as children, the elderly, prisoners, pregnant women, mentally disabled persons or economically or educationally disadvantaged persons, additional safeguards have been included in the research plans, procedures or protocols to protect the rights and welfare of these subjects.

§24108. Grievance Procedure. If application for approval is denied for a research proposal, investigators may appeal to the Dean of the Graduate School & Research. The Dean will appoint an ad hoc committee for a second, independent review of the research project. The findings of the ad hoc committee are presented to the Research Review Committee no later than ninety (90) days after receipt of grievance from investigator, to determine the final decision to approve or not to approve a research project.

§24109. Fines and Penalties. Upon determination of the review board through the approved rules and regulations, any

investigator, research sponsor, or their agents, which conducts research subject to regulation in violation of this chapter shall be subject to a fine of One Thousand Dollars ($1,000.00) per each violation and shall be prohibited from continuing and conducting human research studies for not less than 2 (two) years. "

University of Guam
Unibetsedåt Guahan
OFFICE OF THE PRESIDENT
UOG Station, Mangilao, Guam 96923
Telephone: (671) 735-2990• Fax: (671) 734-2296

May 5, 1998

The Honorable Lawrence Kasperbauer
Chairman, Committee on Education
24th Guam Legislature
155 Hessler Drive
Agana, GU 96910

Re: AN ACT TO CREATE A REVIEW BOARD FOR REVIEW AND APPROVAL OF RESEARCH CONDUCTED ON GUAM WITH REGARD TO HUMAN SUBJECTS.

Dear Chairman Kasperbauer:

I am here today to testify in support of Bill No. 347. This bill proposes to create a Guam Research Review Board for review and approval of research conducted on Guam with regard to human subjects. University administrators and faculty agree that any research on our island must undergo one review process. However, since the Guam Research Review Board would be a duplication of the University of Guam's Committee on Human Subjects in Research (CHSR), I recommend that CHSR, under the Office of Graduate School and Research, be designated as the Institutional Review Board (IRB) for researchers and collaborators at the University and for researchers who are not under other IRBs.

It is noted that there is no mention of additional financial or human resources to accomplish the numerous tasks as specified in the bill. At the present time, Graduate School and Research has only three employees listed in its staffing pattern, and each of these employees has a clearly defined job description and delineated tasks. To comply with the bill's proposed tasks, it is essential to add one clerical staff position and funding for a computer, office furniture, and supplies. In addition, funds would be needed for advertising or informing the community about the Committee on Human Subjects in Research to assure that researchers submit research proposals for review.

Sincerely,

Dr. Jose T. Nededog

JOHN C. STEELE, M.D., FRCP(C)

NEUROLOGIST
FELLOW, AMERICAN COLLEGE OF PHYSICIANS

Tel/Fax: (671) 828-3000

May 11, 1998

Senator Lawrence F. Kasperbauer
Chairman, Committee on Education
Twenty-Fourth Guam Legislature

Dear Dr. Kasperbauer

I am writing to provide testimony about Bill 347 to "create a review board for review and approval of research conducted on Guam with regard to human subjects".

I agree with the intent of the Bill but I have concerns about the mechanism it proposes to achieve the intent. It is a bill which proposes a " fox to guard the hen house"

That intent of bill 347 is to be certain that all medical research on Guam is reviewed and approved by a Committee which will assure protection of human subjects.

In October 1995 at a Legislative Oversight Hearing about lytico-bodig research on Guam which was chaired by Senator Leon Guerrero all participants, including myself agreed that such review and approval was desireable.

After that Oversight Hearing, Dr. Ulla Craig and her medical research associate Dr. Wigbert Wiederholt composed this Bill at the request of Senator Lou Leon Guerrero. However many of us disagreed that the authority of this process should rest in Dr. Craig's Division at the University of Guam, since she and Dr. Wiederholt were pursuing their own exclusive human subject studies of lytico-bodig there. We felt there would be a conflict of interest and that putting the authority with them could jeopordize similar and competing studies by myself and other scienticists wishing to conduct research on Guam.

Senator Leon Guerrero understood that and set the Bill aside.

However, because we agreed that peer review of research was necessary, after the 1995 Oversight Hearing the Hospital formed an Institutional Review Board (IRB) to review research proposals concerned with human subjects. This Hospital Committee meets regularly and it follows Federal guideleines. It is chaired by the GMH Administrator and constituted by members from the Hospital staff and community. The IRB reviews and approves all research conducted under its auspices, including my own.

HCR 18118 • Umatac, Guam 96918 • E- Mail: JSTEELE@KUENTOS•GUAM•NET

As the competition to find the cause of lytico-bodig mounts between teams led by Dr. Wiederholt and myself, Senator Leon Guerrero is introducing the original Bill which Drs Craig and Wiederholt developed in 1995. Because she is a member of their Community Advisory Committee and therefore likely to be biased in their favor, I understand the Bill is being introduced under your auspices. It is cosponsored by Senator Ada but Senator Flores has recently withdrawn his support for it.

Bill 347 proposes another Committee to review research involving human subjects. Although it will be constituted by a representative from the GMH IRB and University of Guam Human Subjects Committee, it will supercede the authority of each and both. Furthermore it places authority for research involving human subjects into the hands of the UOG Graduate School, of which Drs. Craig and Wiederholt are a part. It vests medical research decision making at the University and there is little question but that the authority of section 24105 will be used to restrict and perhaps end studies of lytico-bodig by myself and my colleagues, Professors John Hardy, geneticist at Mayo Clinic, Teepu Siddique, molecular geneticist at Northwestern University, Nicholas Wood geneticist at the National Hospital, London UK, and Patrrick McGeer, immunopathologist at the University of British Columbia.

To ensure fairness and to avoid discrimination against our studies by Drs. Craig and Wiederholt, I am requesting that the authority for reviewing and approving research involving human subjects remains with the (established) GMH IRB and UOG Human Subjects Committee. To ensure protection for human subjects, I recommend that you and your Committee mandate prior approval of all human subject research by one or other Committee, subject to the fines and penalties of Section 24109, if investigators fail to comply.

Your favorable decision of these recommendations will ensure fairness in research and avoid the possability of discrimination against my studies by Drs. Craig and Wiederholt, and members of the UOG Graduate School.

I thank you.

John Steele

John C. Steele MD
Neurologist

Madeleine Z. Bordallo, President of the Guam Lytico & Bodig Association
Norbert Perez, President of the Republic of Guahan
Tyrone Taitano, Chairman GMH IRB
Professor John Hardy, Professor of Pharmacology Mayo Clinic Jacksonville
Professor Teepu Siddique, Director Neurogenetics Laboratory, Nothwestern University
Professor Nicholas Wood, Department of Genetics, National Hospital Queen Square
Professor Patrick McGeer, Kinsmen Laboraotory of Neurological research, Vancouver
Dr. Marcelle Morrison-Bogorad, Associate Director of Neuroscienc and Neurophysiology of Aging Program, National Institute of Aging

Tanya

GUAM LYTICO AND BODIG ASSOCIATION
P.O. Box 1458 Agana, Guam 96932
Tel: (671) 477-2293 • Fax: (671) 477-2294

May 11, 1998

Senator Lawrence F. Kaperbauer
Chairman, Committee on Education
215-A Chalan Santo Papa, Suite 106 F
Ada's Professional & Commercial Center
Agana, Guam 96932

Dear Senator Kasperbauer,

Thank you for soliciting comments and views of the Guam Lytico and Bodig Association about "Bill No. 347: Relative to the creation of a Review Board (at the University of Guam) for review and approval of research conducted on Guam with regard to human subjects."

We agree that all research involving human subjects should be reviewed by a human subjects committee and that all investigators conducting such research should be required to have approval for their studies.

We have a number of specific concerns about Bill 347 which we wish to share with you and your committee.

1. There are already two review boards on Guam with this purpose. The Human Subjects Review Committee at the University of Guam is mandated to provide protection for human subjects participating in research. Another human subjects review board is sited at the Guam Memorial Hospital. That Institutional Review Board Committee (IRB) is formed by members from the community and hospital as recommended by Federal IRB regulations. Its statutes also follow guidelines pertaining to the participation of human subject in research. The Human Subjects Committees at the University of Guam, and Hospital are fully operational and follow Federal guidelines. We therefore do see any advantage or need of another Committee in another part of the University to supersede the authority of these established and existing Committees. Furthermore, we see no reason for disenfrachising the current review boards and having a third review board replace them.

2. We have specific interests about the research of lytico and bodig , whose patients we represent. We are therefore concerned that the supervision of lytico and bodig research will be decided by a non-medical committee on which there is no designated physician or medical scientist. We feel that this lay committee will not accurately interpret, evaluate and approve medical research proposals and the scientists who conduct them.

3. We feel that the description of the legal rights of subjects (§2410G, line 12-15 page 6) should be explicit and that this should include their rights to commercial and economic benefits of the research. The term legal rights in respect to individual, our community and Government needs to be clearly defined.

We recommend that the existing IRBs at GMH and UOG be modified to incorporate the advantages that you foresee in the new review board. If redeligation of authority is not possible, then we hope you will redraft the present Bill to clarify the concerns we have raised.

Thank you for consulting me and the Guam Lytico and Bodig Association in this matter.

Sincerely,

Zeny C. Custodio
PROJECT & AMINISTRATIVE DIRECTOR

Testimony for Bill No. 347

Distinguished Senators,
Buenas yan hafa adai.

My name is **Gregoria Smith,** currently serving as the psychometrist for the UOG/ UCSD Research project on Litigo and Bodig Research. I speak in favor of the intent of Bill 347. First, I wish to commend the introducers of this bill as it is time to define what research is on Guam. However, I would like to suggest that a corresponding mechanism of imposing fines to violators be included . Whether the Attorney General's office should be the investigating agency and where the collected fines should go are issues that may be included as amendments.

As an associate professor at the University of Guam for 25 years, I have done social science research on the culture of the peoples of the Western Pacific. These past few years, I have researched on the **Meaning of Illness and Coping with ALS and Parkinsonism Dementia**. Since they involve human subjects, all of the researches that I have done had to go through institutional review boards of New York University, UOG, or of the Federal agencies for whom I performed the studies and who funded the studies.

Going through review boards and obtaining consent from participants are processes that are **necessary in the practice of research**, a practice that has come from past histories of unknowing subjects being physically harmed by experiments, subjects who have appeared in films and printed media without their consent. I look at this bill as not necessarily one that would hamper any prospective researcher but one intended to **protect the rights of those who participate.**

I believe that among these rights are that the **researcher be trained** in conducting a proper investigation or that he/she be **supervised by**

someone or agency who is knowledgeable on ethical conduct of researchers. Being a doctor, teacher or a social worker, for instance, does not always mean a person can conduct research. One may be a good, honest, knowledgeable doctor / teacher but a poor or inept researcher. **Research, especially scientific research, requires special training** in many skills among which is understanding the language of statistics and a knowledge of the various steps one follows in administering the project. If it is complex, it might require knowledge of the project's algorithm, requiring decision-making in every step of the way. This is why most researches are conducted under the auspices of either the federal government, educational institutions or foundations who conduct training courses for the discipline of research.

Training for research includes among other things, knowledge and explication of the **"methodology"** being proposed that would fit the **stated objectives** of the project. One can not just think of something and say he wants to do research on it. One has to have **hypotheses** and say how he/she is going to prove that his results are going to make a significant difference from what we assume to be normal in the general scheme of things. The **tests have to be rigorous** so that the results can withstand the scrutiny of other scientists who are conducting related studies. For there is a society of scholars to whom one communicates and shares knowledge with. One hopes that the results of one's studies would lead to a different way of looking at something whether it is a disease, specie in nature or the relationship among categories or concepts we are familiar with .

Needless to say, the ultimate benefactors of the results of one's scholarly efforts are neither the conductor of the research although he may be recognized by his peers in one way or another nor the assistants who provide so-called leg work for the researcher. **The real benefactors are those whose quality of living will be made better** by such a discovery and the young inquisitive minds who will push off from where we leave, either to affirm or negate our findings. The scholars and

stakeholders in this deliberation today must then, recognize that **it is the community at large and humanity** in general who would benefit from the results. In order to do this we must all safeguard the quality of researches performed here and that they be done in the **strictest ethical standards that show respect to those people** without whom we will not be able to conduct our studies.

This bill will objectify what some of us are doing in the name of "Research". It will make us accountable for what we do in its name and will enforce the standards that are recognized most anywhere else.

Thank you for your kind attention.

Gregoria Smith
Community Psychologist
Tel/ Fax 649 7571

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FAX

DATE: 5 May 1998

TO: The Honorable Lawrence F. Kasperbauer, Senator, Chair, Committee on Education — FAX: 671-475-2000

FROM: Dr. Marcus C. Tye, Asst. Professor, Psychology, University of Guam — PHONE: 671-735-2886; FAX: 671-734-5255

C: Dr. Mary L. Spencer, Dean, College of Arts & Sciences, UOG
Dr. Ulla-Katrina Craig, Chair, Committee on Human Research Subjects, UOG
Dr. Joyce Marie Camacho, Acting Dean, Graduate School & Research, UOG

Number of pages including this page: 1

RE: Bill No. 347, An Act to Create a Review Board for Review and Approval of Research Conducted on Guam with Regard to Human Subjects

Message:

Dear Senator Kasperbauer,

I write to urge you to lobby against Bill No. 347. I am a faculty member of the University of Guam where I am engaged in an active program of research, as are many of my colleagues. Research is of intrinsic benefit to the community (both here on Guam and elsewhere) and directly helps student learning. I take pride in the support for research that is being fostered at the University of Guam and am puzzled by Bill No. 347. The spirit of the bill is fully appropriate—it is indeed important to be concerned first for the welfare of human subjects and to protect human subjects—what is puzzling to me is the need for such a bill, especially one that constrains research done at the University, since UOG already has a review process that very carefully monitors research. Some of the many reasons against this bill include:

1. Such a law would be largely unprecedented. Virtually all jurisdictions in the US and many other countries allow universities and hospitals to administer research internally. Indeed, UOG already has an excellent institutional review panel, the Committee on Human Research Subjects.

2. Even the proposal of such a law is disturbing as it gives the appearance that our island's government fails to understand (and perhaps fails to value) research and the University.

3. Simple student research projects would become almost impossible because of the burden of going to a committee outside the university, and reductions in research would detract from the quality of undergraduate education at the University of Guam.

4. The passage of such a law would seriously undermine the efforts of faculty to bring in research money, which traditionally helps support the host institution. It also adds to Guam's already large bureaucracy.

Thank you for your time and your efforts in ensuring that this bill does not pass, or at the very least to make sure the bill is amended to exempt any research conducted on Guam that receives approval from UOG's existing internal Committee on Human Research Subjects

Sincerely,

M. C. Tye, Ph.D.

Definitions

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Research subject to regulation encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity. It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (e.g., Wage/Hour requirements administered by the Department of Labor).

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Certification means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

Purpose

The CHRS evaluates the level of risk to human subjects, recommends procedural steps to minimize risks, and provides certification as needed by the researcher. It does not judge research design nor recommend methodological alternatives. Under federal regulations, the CHRS is charged with safeguarding the rights and welfare of humans involved, and must determine:

- **whether the rights and welfare of the humans involved in research will be adequately protected, and**
- **whether legally effective informed consent of all humans to be solicited will be obtained with adequate records maintained (request CHRS Informed Consent Guidelines, Form B and C).**

Procedures

1. Obtain an application for CHRS review (Form A) from the UOG Office of the Graduate School and Research. Include copies of the project proposal, all consent forms, and summary scripts of verbal and/or video instructions to be delivered to subjects.

2. Maintain working contact with the CHRS Chair during the review process, and provide supplemental information as requested by the committee or submit a reply to suggested considerations.

3. If approved, research projects may be monitored by the CHRS as needed to ensure due process and protection of rights for the human subjects involved.

UNIVERSITY OF GUAM

Committee on Human Research Subjects
Office of the Graduate School and Research

RESEARCH SUBJECT'S BILL OF RIGHTS

Any person who is requested to consent to participate as a subject in a research project, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the research study, and drugs or device to be used.

3. Be given a description of any possible discomfort and risks reasonably to be expected from a research procedure, if applicable.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the research procedure, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantages to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.

8. Be instructed that consent to participate in the research study may be withdrawn at any time, and the subject may discontinue participation in the research study without prejudice.

9. Be given a copy of a signed and dated written consent form when one is required.

10. Be given the opportunity to decide to consent or not to consent to participate in a research study without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

If you have a question regarding the research study, the researcher or other research personnel will be glad to answer them. You may seek information from the UOG Committee for Human Research Subjects—established for the protection of participants in research projects—by calling 735-2173 (UOG Graduate School & Research) from 8 am to 5 pm, Monday through Friday, or by writing to the above address.

informed consent of human subjects as a condition of performing research involving the Commonwealth's facilities, services or funds".

Institutional Review Boards: Composition and Oversight Responsibilities indicates the main "oversight" mechanism in human subjects research is the local Institutional Review Board (IRB), and the concerns which motivate the national commission to recommend "systematic, non-arbitrary analysis of risks and benefits" are clearly discernible from the federal regulations which govern their composition and function. The federal "assurance" requirement is that IRBs be groups of highly competent professional and lay persons, who are free of direct conflicts of interest, well-qualified by reference either to professional training, experience in their respective fields of endeavor, personal background, and position in the community and who are sensitive to the moral, cultural, legal, professional, and ethical questions which arise whenever human subjects are used in biomedical and behavioral research.

I respectfully request that the Guam Bill #347 be reviewed in context of these federal guidelines, and recognize them as setting the standards for acceptable research behavior.

Yours sincerely,

Dr. Pamina J. Hofer
Guam License CP#[illegible]2

Pamina J. Hofer, Ph.D.
Clinical Neuropsychologist

P.O. Box 5208
Univ. of Guam Station
Mangilao, GU 96923-5208

May 6, 1998

Attn: Larry Kasperbauer
Committee on Education, Guam Legislature
by facsimile only 475-2000

Re: Proposed Bill #347

Dear Esteemed Senators:

I am a private practitioner, who is very concerned about the negative ramifications of the proposed Bill #347 which seeks to limit research by reviewing all such proposals through a governmentally sponsored Human Subjects Committee. There are already a host of US Federal government regulations which relate to the general integrity of the research process. Among these are institutional and federal regulations which prohibit financial fraud and abuse, including conflicts of interest, and institutional, administrative and other rules which prohibit research and other forms of academic fraud.

As a Clinical Psychologist, I am further bound by the ethics code set forth by the American Psychological Association (1991, see attached). Moreover, I maintain an adjunct position with the University of Guam in order that I may obtain federal grants for research, as these are only allowed in settings where the 'institution has a formal Human Subjects Review procedure'.

Most frequently, however, my research involves scientific discovery which occurs following direct service provision (assessments and therapy) which were not originally planned to be research-oriented. For example, I presented a paper at the recent annual meetings of the National Academy of Neuropsychology regarding the test measures which are best to use to estimate intelligence in a multicultural setting (such as Guam), based on the findings of 45 recent referrals from the Department of Vocational Rehabilitation. To be fined for presenting such discovery to my colleagues would be tantamount to fining an individual who recognizes a round object with a hole in the middle might facilitate transport.

Professor Jesse Goldner has noted that in order to "understand the scheme which currently controls the circumstances under which biomedical and behavioral research involving human subjects can take place, there is a need to have some familiarity with (1) the recent history of formal experimentation with human subjects and (2) the ethical principles which have now been identified as necessarily underlying the conduct of such research."[1] In my opinion, the proposed legislation does not fit this protocol, as the proposed component individuals will not have training in either the experimental methodology or current ethical practices in Clinical Psychology. Moreover, it is at odds with the National Research Act and the Belmont Report, as it seeks to regulate rather than provide oversight (post facto opinion only) of human subjects' research.

At present, seven states (California, Wisconsin, New York, Delaware, Montana, Florida, and Virginia) have statues which govern human subjects research, and none of them attempt to dictate the quality or ethical standards of this research through their own ethical review panel. Rather, they "require the

Phone: (671) 734-0382
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1.08 Human Differences

Where differences of age, gender, race, ethnicity, national origin, religion, sexual orientation, disability, language, or socioeconomic status significantly affect psychologists' work concerning particular individuals or groups, psychologists obtain the training, experience, consultation, or supervision necessary to ensure the competence of their services, or they make appropriate referrals.

1.09 Respecting Others

In their work-related activities, psychologists respect the rights of others to hold values, attitudes, and opinions that differ from their own.

1.10 Nondiscrimination

In their work-related activities, psychologists do not engage in unfair discrimination based on age, gender, race, ethnicity, national origin, religion, sexual orientation, disability, socioeconomic status, or any basis proscribed by law.

1.11 Sexual Harassment

(a) Psychologists do not engage in sexual harassment. Sexual harassment is sexual solicitation, physical advances, or verbal or nonverbal conduct that is sexual in nature, that occurs in connection with the psychologist's activities or roles as a psychologist, and that either: (1) is unwelcome, is offensive, or creates a hostile workplace environment, and the psychologist knows or is told this; or (2) is sufficiently severe or intense to be abusive to a reasonable person in the context. Sexual harassment can consist of a single intense or severe act or of multiple persistent or pervasive acts.

(b) Psychologists accord sexual-harassment complainants and respondents dignity and respect. Psychologists do not participate in denying a person academic admittance or advancement, employment, tenure, or promotion, based solely upon their having made, or their being the subject of, sexual-harassment charges. This does not preclude taking action based upon the outcome of such proceedings or consideration of other appropriate information.

1.12 Other Harassment

Psychologists do not knowingly engage in behavior that is harassing or demeaning to persons with whom they interact in their work based on factors such as those persons' age, gender, race, ethnicity, national origin, religion, sexual orientation, disability, language, or socioeconomic status.

1.13 Personal Problems and Conflicts

(a) Psychologists recognize that their personal problems and conflicts may interfere with their effectiveness. Accordingly, they refrain from undertaking an activity when they know or should know that their personal problems are likely to lead to harm to a patient, client, colleague, student, research participant, or other person to whom they may owe a professional or scientific obligation.

(b) In addition, psychologists have an obligation to be alert to signs of, and to obtain assistance for, their personal problems at an early stage, in order to prevent significantly impaired performance.

(c) When psychologists become aware of personal problems that may interfere with their performing work-related duties adequately, they take appropriate measures, such as obtaining professional consultation or assistance, and determine whether they should limit, suspend, or terminate their work-related duties.

1.14 Avoiding Harm

Psychologists take reasonable steps to avoid harming their patients or clients, research participants, students, and others with whom they work, and to minimize harm where it is foreseeable and unavoidable.

1.15 Misuse of Psychologists' Influence

Because psychologists' scientific and professional judgments and actions may affect the lives of others, they are alert to and guard against personal, financial, social, organizational, or political factors that might lead to misuse of their influence.

1.16 Misuse of Psychologists' Work

(a) Psychologists do not participate in activities in which it appears likely that their skills or data will be misused by others, unless corrective mechanisms are available. (See also Standard 7.04, Truthfulness and Candor.)

(b) If psychologists learn of misuse or misrepresentation of their work, they take reasonable steps to correct or minimize the misuse or misrepresentation.

1.17 Multiple Relationships

(a) In many communities and situations, it may not be feasible or reasonable for psychologists to avoid social or other nonprofessional contacts with persons such as patients, clients, students, supervisees, or research participants. Psychologists must always be sensitive to the potential harmful effects of other contacts on their work and on those persons with whom they deal. A psychologist refrains from entering into or promising another personal, scientific, professional, financial, or other relationship with such persons if it appears likely that such a relationship reasonably might impair the psychologist's objectivity or otherwise interfere with the psychologist's effectively performing his or her functions as a psychologist, or might harm or exploit the other party.

(b) Likewise, whenever feasible, a psychologist refrains from taking on professional or scientific obligations when preexisting relationships would create a risk of such harm.

(c) If a psychologist finds that, due to unforeseen factors, a potentially harmful multiple relationship has arisen, the psychologist attempts to resolve it with due regard for the best interests of the affected person and maximal compliance with the Ethics Code.

Psychologists try to eliminate the effect on their work of biases based on those factors, and they do not knowingly participate in or condone unfair discriminatory practices.

Principle E: Concern for Others' Welfare

Psychologists seek to contribute to the welfare of those with whom they interact professionally. In their professional actions, psychologists weigh the welfare and rights of their patients or clients, students, supervisees, human research participants, and other affected persons, and the welfare of animal subjects of research. When conflicts occur among psychologists' obligations or concerns, they attempt to resolve these conflicts and to perform their roles in a responsible fashion that avoids or minimizes harm. Psychologists are sensitive to real and ascribed differences in power between themselves and others, and they do not exploit or mislead other people during or after professional relationships.

Principle F: Social Responsibility

Psychologists are aware of their professional and scientific responsibilities to the community and the society in which they work and live. They apply and make public their knowledge of psychology in order to contribute to human welfare. Psychologists are concerned about and work to mitigate the causes of human suffering. When undertaking research, they strive to advance human welfare and the science of psychology. Psychologists try to avoid misuse of their work. Psychologists comply with the law and encourage the development of law and social policy that serve the interests of their patients and clients and the public. They are encouraged to contribute a portion of their professional time for little or no personal advantage.

ETHICAL STANDARDS

1. General Standards

These General Standards are potentially applicable to the professional and scientific activities of all psychologists.

1.01 Applicability of the Ethics Code

The activity of a psychologist subject to the Ethics Code may be reviewed under these Ethical Standards only if the activity is part of his or her work-related functions or the activity is psychological in nature. Personal activities having no connection to or effect on psychological roles are not subject to the Ethics Code.

1.02 Relationship of Ethics and Law

If psychologists' ethical responsibilities conflict with law, psychologists make known their commitment to the Ethics Code and take steps to resolve the conflict in a responsible manner.

1.03 Professional and Scientific Relationship

Psychologists provide diagnostic, therapeutic, teaching, research, supervisory, consultative, or other psychological services only in the context of a defined professional or scientific relationship or role. (See also Standards 2.01, Evaluation, Diagnosis, and Interventions in Professional Context, and 7.02, Forensic Assessments.)

1.04 Boundaries of Competence

(a) Psychologists provide services, teach, and conduct research only within the boundaries of their competence, based on their education, training, supervised experience, or appropriate professional experience.

(b) Psychologists provide services, teach, or conduct research in new areas or involving new techniques only after first undertaking appropriate study, training, supervision, and/or consultation from persons who are competent in those areas or techniques.

(c) In those emerging areas in which generally recognized standards for preparatory training do not yet exist, psychologists nevertheless take reasonable steps to ensure the competence of their work and to protect patients, clients, students, research participants, and others from harm.

1.05 Maintaining Expertise

Psychologists who engage in assessment, therapy, teaching, research, organizational consulting, or other professional activities maintain a reasonable level of awareness of current scientific and professional information in their fields of activity, and undertake ongoing efforts to maintain competence in the skills they use.

1.06 Basis for Scientific and Professional Judgments

Psychologists rely on scientifically and professionally derived knowledge when making scientific or professional judgments or when engaging in scholarly or professional endeavors.

1.07 Describing the Nature and Results of Psychological Services

(a) When psychologists provide assessment, evaluation, treatment, counseling, supervision, teaching, consultation, research, or other psychological services to an individual, a group, or an organization, they provide, using language that is reasonably understandable to the recipient of those services, appropriate information beforehand about the nature of such services and appropriate information later about results and conclusions. (See also Standard 2.09, Explaining Assessment Results.)

(b) If psychologists will be precluded by law or by organizational roles from providing such information to particular individuals or groups, they so inform those individuals or groups at the outset of the service.

APA membership, and referral of the matter to other bodies. Complainants who seek remedies such as monetary damages in alleging ethical violations by a psychologist must resort to private negotiation, administrative bodies, or the courts. Actions that violate the Ethics Code may lead to the imposition of sanctions on a psychologist by bodies other than APA, including state psychological associations, other professional groups, psychology boards, other state or federal agencies, and payors for health services. In addition to actions for violation of the Ethics Code, the APA Bylaws provide that APA may take action against a member after his or her conviction of a felony, expulsion or suspension from an affiliated state psychological association, or suspension or loss of licensure.

PREAMBLE

Psychologists work to develop a valid and reliable body of scientific knowledge based on research. They may apply that knowledge to human behavior in a variety of contexts. In doing so, they perform many roles, such as researcher, educator, diagnostician, therapist, supervisor, consultant, administrator, social interventionist, and expert witness. Their goal is to broaden knowledge of behavior and, where appropriate, to apply it pragmatically to improve the condition of both the individual and society. Psychologists respect the central importance of freedom of inquiry and expression in research, teaching, and publication. They also strive to help the public in developing informed judgments and choices concerning human behavior. This Ethics Code provides a common set of values upon which psychologists build their professional and scientific work.

This Code is intended to provide both the general principles and the decision rules to cover most situations encountered by psychologists. It has as its primary goal the welfare and protection of the individuals and groups with whom psychologists work. It is the individual responsibility of each psychologist to aspire to the highest possible standards of conduct. Psychologists respect and protect human and civil rights, and do not knowingly participate in or condone unfair discriminatory practices.

The development of a dynamic set of ethical standards for a psychologist's work-related conduct requires a personal commitment to a lifelong effort to act ethically; to encourage ethical behavior by students, supervisees, employees, and colleagues, as appropriate; and to consult with others, as needed, concerning ethical problems. Each psychologist supplements, but does not violate, the Ethics Code's values and rules on the basis of guidance drawn from personal values, culture, and experience.

GENERAL PRINCIPLES

Principle A: Competence

Psychologists strive to maintain high standards of competence in their work. They recognize the boundaries of their particular competencies and the limitations of their expertise. They provide only those services and use only those techniques for which they are qualified by education, training, or experience. Psychologists are cognizant of the fact that the competencies required in serving, teaching, and/or studying groups of people vary with the distinctive characteristics of those groups. In those areas in which recognized professional standards do not yet exist, psychologists exercise careful judgment and take appropriate precautions to protect the welfare of those with whom they work. They maintain knowledge of relevant scientific and professional information related to the services they render, and they recognize the need for ongoing education. Psychologists make appropriate use of scientific, professional, technical, and administrative resources.

Principle B: Integrity

Psychologists seek to promote integrity in the science, teaching, and practice of psychology. In these activities psychologists are honest, fair, and respectful of others. In describing or reporting their qualifications, services, products, fees, research, or teaching, they do not make statements that are false, misleading, or deceptive. Psychologists strive to be aware of their own belief systems, values, needs, and limitations and the effect of these on their work. To the extent feasible, they attempt to clarify for relevant parties the roles they are performing and to function appropriately in accordance with those roles. Psychologists avoid improper and potentially harmful dual relationships.

Principle C: Professional and Scientific Responsibility

Psychologists uphold professional standards of conduct, clarify their professional roles and obligations, accept appropriate responsibility for their behavior, and adapt their methods to the needs of different populations. Psychologists consult with, refer to, or cooperate with other professionals and institutions to the extent needed to serve the best interests of their patients, clients, or other recipients of their services. Psychologists' moral standards and conduct are personal matters to the same degree as is true for any other person, except as psychologists' conduct may compromise their professional responsibilities or reduce the public's trust in psychology and psychologists. Psychologists are concerned about the ethical compliance of their colleagues' scientific and professional conduct. When appropriate, they consult with colleagues in order to prevent or avoid unethical conduct.

Principle D: Respect for People's Rights and Dignity

Psychologists accord appropriate respect to the fundamental rights, dignity, and worth of all people. They respect the rights of individuals to privacy, confidentiality, self-determination, and autonomy, mindful that legal and other obligations may lead to inconsistency and conflict with the exercise of these rights. Psychologists are aware of cultural, individual, and role differences, including those due to age, gender, race, ethnicity, national origin, religion, sexual orientation, disability, language, and socioeconomic status,

INTRODUCTION

The American Psychological Association's (APA's) Ethical Principles of Psychologists and Code of Conduct (hereinafter referred to as the Ethics Code) consists of an Introduction, a Preamble, six General Principles (A–F), and specific Ethical Standards. The Introduction discusses the intent, organization, procedural considerations, and scope of application of the Ethics Code. The Preamble and General Principles are *aspirational* goals to guide psychologists toward the highest ideals of psychology. Although the Preamble and General Principles are not themselves enforceable rules, they should be considered by psychologists in arriving at an ethical course of action and may be considered by ethics bodies in interpreting the Ethical Standards. The Ethical Standards set forth *enforceable* rules for conduct as psychologists. Most of the Ethical Standards are written broadly, in order to apply to psychologists in varied roles, although the application of an Ethical Standard may vary depending on the context. The Ethical Standards are not exhaustive. The fact that a given conduct is not specifically addressed by the Ethics Code does not mean that it is necessarily either ethical or unethical.

Membership in the APA commits members to adhere to the APA Ethics Code and to the rules and procedures used to implement it. Psychologists and students, whether or not they are APA members, should be aware that the Ethics Code may be applied to them by state psychology boards, courts, or other public bodies.

This Ethics Code applies only to psychologists' work-related activities, that is, activities that are part of the psychologists' scientific and professional functions or that are psychological in nature. It includes the clinical or counseling practice of psychology, research, teaching, supervision of trainees, development of assessment instruments, conducting assessments, educational counseling, organizational consulting, social intervention, administration, and other activities as well. These work-related activities can be distinguished from the purely private conduct of a psychologist, which ordinarily is not within the purview of the Ethics Code.

The Ethics Code is intended to provide standards of professional conduct that can be applied by the APA and by other bodies that choose to adopt them. Whether or not a psychologist has violated the Ethics Code does not by itself determine whether he or she is legally liable in a court action, whether a contract is enforceable, or whether other legal consequences occur. These results are based on legal rather than ethical rules. However, compliance with or violation of the Ethics Code may be admissible as evidence in some legal proceedings, depending on the circumstances.

In the process of making decisions regarding their professional behavior, psychologists must consider this Ethics Code, in addition to applicable laws and psychology board regulations. If the Ethics Code establishes a higher standard of conduct than is required by law, psychologists must meet the higher ethical standard. If the Ethics Code standard appears to conflict with the requirements of law, then psychologists make known their commitment to the Ethics Code and take steps to resolve the conflict in a responsible manner. If neither law nor the Ethics Code resolves an issue, psychologists should consider other professional materials[1] and the dictates of their own conscience, as well as seek consultation with others within the field when this is practical.

The procedures for filing, investigating, and resolving complaints of unethical conduct are described in the current Rules and Procedures of the APA Ethics Committee. The actions that APA may take for violations of the Ethics Code include actions such as reprimand, censure, termination of

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This version of the APA Ethics Code was adopted by the American Psychological Association's Council of Representatives during its meeting, August 13 and 16, 1992, and is effective beginning December 1, 1992. Inquiries concerning the substance or interpretation of the APA Ethics Code should be addressed to the Director, Office of Ethics, American Psychological Association, 750 First Street, NE, Washington, DC 20002-4242.

This Code will be used to adjudicate complaints brought concerning alleged conduct occurring on or after the effective date. Complaints regarding conduct occurring prior to the effective date will be adjudicated on the basis of the version of the Code that was in effect at the time the conduct occurred, except that no provisions repealed in June 1989, will be enforced even if an earlier version contains the provision. The Ethics Code will undergo continuing review and study for future revisions; comments on the Code may be sent to the above address.

The APA has previously published its Ethical Standards as follows:

American Psychological Association. (1953). *Ethical standards of psychologists*. Washington, DC: Author.

American Psychological Association. (1958). Standards of ethical behavior for psychologists. *American Psychologist, 13*, 268–271.

American Psychological Association. (1963). Ethical standards of psychologists. *American Psychologist, 18*, 56–60.

American Psychological Association. (1968). Ethical standards of psychologists. *American Psychologist, 23*, 357–361.

American Psychological Association. (1977, March). Ethical standards of psychologists. *APA Monitor*, pp. 22–23.

American Psychological Association. (1979). *Ethical standards of psychologists*. Washington, DC: Author.

American Psychological Association. (1981). Ethical principles of psychologists. *American Psychologist, 36*, 633–638.

American Psychological Association. (1990). Ethical principles of psychologists (Amended June 2, 1989). *American Psychologist, 45*, 390–395.

Request copies of the APA's Ethical Principles of Psychologists and Code of Conduct from the APA Order Department, 750 First Street, NE, Washington, DC 20002-4242, or phone (202) 336-5510.

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[1]Professional materials that are most helpful in this regard are guidelines and standards that have been adopted or endorsed by professional psychological organizations. Such guidelines and standards, whether adopted by the American Psychological Association (APA) or its Divisions, are not enforceable as such by this Ethics Code, but are of educative value to psychologists, courts, and professional bodies. Such materials include, but are not limited to, the APA's *General Guidelines for Providers of Psychological Services* (1987), *Specialty Guidelines for the Delivery of Services by Clinical Psychologists, Counseling Psychologists, Industrial/Organizational Psychologists, and School Psychologists* (1981), *Guidelines for Computer Based Tests and Interpretations* (1987), *Standards for Educational and Psychological Testing* (1985), *Ethical Principles in the Conduct of Research With Human Participants* (1982), *Guidelines for Ethical Conduct in the Care and Use of Animals* (1986), *Guidelines for Providers of Psychological Services to Ethnic, Linguistic, and Culturally Diverse Populations* (1990), and *Publication Manual of the American Psychological Association* (3rd ed., 1983). Materials not adopted by APA as a whole include the APA Division 41 (Forensic Psychology)/American Psychology–Law Society's *Specialty Guidelines for Forensic Psychologists* (1991).

Ethical Principles of Psychologists and Code of Conduct

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AMERICAN
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ASSOCIATION

ETHICAL PRINCIPLES OF PSYCHOLOGISTS AND CODE OF CONDUCT

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- 1 Hospital Administrator
- the President of Medical Staff
- 1 Associate Administrator
- the Chairperson, Department of Surgery
- the Chairperson, Department of Medicine
- the Chief Pathologist
- 1 Staff RN (Registered Nurse)
- the Pastoral Care Coordinator
- 1 University of Guam Committee for Human Subject in Research (CHSR) representative

AND has standing policies that empower the IRB to request and obtain relevant inputs from experts and other resources in areas not represented by the existing IRB members.

Existing Review Boards do not need to be Duplicated

Bill #347 proposes the duplication of the existing research review processes and procedures that are conducted by the UOG Committee for Human Subject in Research (CHSR) and the Guam Memorial Hospital Institutional Review Board (IRB) for Research. THE PEOPLE OF GUAM ARE SUPERBLY PROTECTED BY THE EXISTING REVIEW BOARDS when research is processed through them.

What is needed, in my opinion, is not another Review Board. GUAM NEEDS TO HAVE THE UOG COMMITTEE FOR HUMAN SUBJECT IN RESEARCH (CHSR) DESIGNATED BY THE GUAM LEGISLATURE AS THE REVIEW BODY FOR ALL RESEARCH RELATED TO HUMAN SUBJECTS THAT TAKES PLACE ON GUAM. Further, the existing UOG Policies and Procedures that relate to and govern the CHSR need to be accepted as the standard for Guam. The UOG Committee for Human Subject in Research (CHSR) as it presently exists can probably cope with the volume of work needed to review research on Guam. However logistic support will be needed in the form of an annual monetary allocation to defray office and clerical costs.

To do so, MAJOR REVISION OF BILL #347 APPEARS NECESSARY so that the above can be accomplished. And this will help ensure that the People of Guam will remain protected as they should be. However, ANOTHER REVIEW BOARD as presently proposed IS NOT NEEDED.

THEREFORE, SENATOR KASPERBAUER, I STRONGLY URGE YOU AND YOUR COMMITTEE ON EDUCATION TO RE- CONSIDER THE ARGUMENTS REGARDING BILL #347. I URGE THE COMMITTEE TO MOVE THAT BILL #347 UNDERGO SERIOUS REVISION SO THAT IT WILL EMPOWER AND SUPPORT THE UOG COMMITTEE FOR HUMAN SUBJECT IN RESEARCH (CHSR) with the existing UOG policies and procedures AS THE GUAM RESEARCH REVIEW BOARD FOR HUMAN SUBJECTS.

Dankolo Na Si Yu'os Ma'ase for the opportunity to voice an opinion regarding why Bill #347 should be revised. If I can be of further assistance, please feel free to call on me.

UNIVERSITY OF GUAM
UNIBETSEDÅT GUAHAN

PSYCHOLOGY PROGRAM
DIVISION OF SOCIAL/BEHAVIORAL SCIENCES & SOCIAL WORK
Seyda Türk Smith, Ph. D.
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e-mail: stsmith@uog9.uog.edu

May 4th, 1998

Senator Lawrence F. Kasperbauer
Chairman
Twenty-fourth Guam Legislature
Committee on Education

Reference : Bill #347 Relative to Creating a Guam Research Review Board

As a researcher and an educator teaching research methodology and supervising undergraduate research at the University of Guam, I firmly oppose to the establishment of a new "Guam Research Review Board" that will oversea all research conducted on Guam. This will make undergraduate research impossible to conduct and will deprive UOG students of valuable research experience. I would like to state some of my reasons for this claim:

1. Any research that is conducted at the UOG is being reviewed - and will continue to be reviewed - by the University's Committee on Human Research Subjects to assure "the protection of the rights of persons participating in human research projects." Under the present system, undergraduate researchers working under faculty supervision can design, submit for review, and conduct a study within one semester. Such research , which typically is noninvasive and straightforward - needs only an expedited review, and the approval takes approximately 7-8 days. It will be impossible to fit another review by another Research Review Board to this limited time frame.

2. Given that all undergraduate research is reviewed by the University's Committee on Human Research Subjects, the duplication of this process seems unnecessary and redundant. The University's review board has a good track record and has been able to review research applications and protect the rights of human subjects successfully.

Undergraduate research is an integral part of the curriculum of the UOG Psychology Program. All psychology classes have a research component. Students learn to evaluate research and develop research proposals. At least half of the students taking psychology classes learn to conduct research to answer their questions on topics that are discussed in class. In addition to that, students who apply to graduate school in psychology are

required to have extensive research training and those who have hands-on research experience have advantage over other applicants. It is critical that our students continue to conduct undergraduate research that enriches their learning experience and increases their educational opportunities.

Respectfully,

Seyda Türk Smith

Seyda Türk Smith, Ph. D.
Associate Professor of Psychology

fax copy: Sen. Lou Leon Guerrero

ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH

A Summary of the Belmont Report

The National Commission for the Protection of Human Subjects of Biomedical & Behavioral Research

U.S. Department of Health, Education and Welfare
Published: April 18, 1979

The following consists of quoted excerpts. A copy of the complete report is available in the files of the UOG Committee for Human Research Subjects, Graduate School and Research Office.

INTRODUCTION

Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions.

Since 1945, various codes for the proper and responsible conduct of human experimentation in medical research have been adopted. These are the Nuremberg Code of 1947, the Helsinki Declaration of 1964 (revised 1975), and the 1971 Guidelines (codified into Federal Regulations in 1974) issued by the U.S. Department of Health, Education, and Welfare. Codes for the conduct of social and behavioral research have also been adopted, by the American Psychological Association, 1973.

Three principles, or general prescriptive judgments, that are relevant to research involving human subjects are identified in these statements. These should assist scientists, subjects, reviewers and interested citizens to understand the ethical issues inherent in research involving human subjects.

This report consists of a distinction between research and practice, a discussion of the three basic ethical principles, and remarks about the application of these principles.

undue influences if the subject is especially vulnerable.

Unjustifiable pressures usually occur when persons in positions of authority or commanding influence -- especially where possible sanctions are involved -- urge a course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins.

2. Assessment of Risks and Benefits: presents both an opportunity and a responsibility to gather systematic and comprehensive information about proposed research, including alternative ways of obtaining the benefits sought in the research. For the investigator, it is a means to examine whether the proposed research is properly designed. For a review committee, it is a method for determining whether the risks to subjects are justified.

The term "risk" refers to a possibility that harm may occur. It includes reference both to the chance (probability) of experiencing a harm and the severity (magnitude) of the envisioned harm. The term "benefit" is used to refer to something of positive value related to health, education, knowledge, or welfare. Unlike "risk," "benefit" does not express probabilities. Risk is properly contrasted to probability of benefits, and benefits are properly contrasted with harms rather than risks of harm. Risk/benefit assessments are concerned with the probabilities and magnitudes of possible harms and anticipated benefits.

Many kinds of possible harms and benefits need to be taken into account. There are, for example, risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits. Risk can perhaps never be entirely eliminated, but it can often be reduced by careful attention to alternative procedures.

C. Applications

Applications of the general principles to the conduct of research leads to consideration of the following requirements:

1. Informed Consent: requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. There is widespread agreement that the consent process can be analyzed as containing three elements - information, comprehension and voluntariness.

Information. Most codes of research establish specific items for disclosure intended to assure that subjects are given sufficient information. These items generally include: the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity t ask questions and to withdraw at any time from the research. Additional items have been proposed, including how subjects are selected, the person responsible for the research, etc.

However, a listing of items does not clarify ways for judging how much and what sort of information should be provided. It may be that a standard of "the reasonable volunteer" should be followed: the extent and nature of information should be such that persons, knowing that the procedure is neither necessary nor fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation.

Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research.

Comprehension. The manner and context in which information is conveyed is as important as the information itself. For example, presenting information in a disorganized and rapid fashion, allowing too little time for consideration or curtailing opportunities for questioning, all may adversely affect a subject's ability to make an informed choice.

Because the subject's ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the subject's capacities. Investigators are responsible for ascertaining that the subject has comprehended the information.

Voluntariness. This element of informed consent requires conditions free of coercion and undue influence. Undue influence occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become

hand, it would seem that respect requires that prisoners and students not be deprived of the opportunity to volunteer for research. On the other hand, under prison and classroom conditions both may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer.

2. Beneficence: is a term often understood to cover acts of kindness or charity that go beyond strict obligations. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules are complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.

The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation.

A difficult ethical problem remains about research that presents more than minimal risk without immediate prospects of direct benefit to the subjects involved. Some have argued that such research is inadmissible, while others have pointed out that this limit would rule out research promising great benefit to people in the future. As with all hard cases, the different claims covered by the principle of beneficence -- benefits versus harms -- may come into conflict and force difficulty choices.

3. Justice: asks Who ought to receive the benefits of research and bear its burdens? This is a question of "fairness in distribution" or " what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly.

The selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, racial, ethnic, and gender minorities, or persons in institutional settings) are being systematically selected or excluded simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Justice demands both that research not provide advantages only to certain persons or groups, and that such research should not fail to direct benefits toward those involved.

A. Boundaries Between Practice and Research

It is important to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergo review for the protection of human subjects of research. The distinction between research and practice is blurred partly because both often occur together (as in research designed to evaluate a therapy).

The term "practice" refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. By contrast, the term "research" designates an activity designed to test an hypothesis, permit conclusions to be drawn, and/or develop and contribute to knowledge (expressed, for example, in theories, principles, statements of relationship, and descriptive summary).

Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research, that activity should undergo review for the protection of human subjects.

B. Basic Ethical Principles

1. Respect for Persons: incorporates at least two ethical convictions; first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices. To show lack of respect for an autonomous agent is to repudiate that person's considered judgements, to deny an individual the freedom to act on those considered judgements, or to withhold information necessary to make a considered judgement.

The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

Respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners, at one extreme, or of students in more normal circumstances, provide instructive examples. On the one

early as is feasible. (See also Standard 4.08, Interruption of Services.)

(f) If the patient, client, or other recipient of services does not pay for services as agreed, and if the psychologist wishes to use collection agencies or legal measures to collect the fees, the psychologist first informs the person that such measures will be taken and provides that person an opportunity to make prompt payment. (See also Standard 5.11, Withholding Records for Nonpayment.)

1.26 Accuracy in Reports to Payors and Funding Sources

In their reports to payors for services or sources of research funding, psychologists accurately state the nature of the research or service provided, the fees or charges, and where applicable, the identity of the provider, the findings, and the diagnosis. (See also Standard 5.05, Disclosures.)

1.27 Referrals and Fees

When a psychologist pays, receives payment from, or divides fees with another professional other than in an employer–employee relationship, the payment to each is based on the services (clinical, consultative, administrative, or other) provided and is not based on the referral itself.

2. Evaluation, Assessment, or Intervention

2.01 Evaluation, Diagnosis, and Interventions in Professional Context

(a) Psychologists perform evaluations, diagnostic services, or interventions only within the context of a defined professional relationship. (See also Standard 1.03, Professional and Scientific Relationship.)

(b) Psychologists' assessments, recommendations, reports, and psychological diagnostic or evaluative statements are based on information and techniques (including personal interviews of the individual when appropriate) sufficient to provide appropriate substantiation for their findings. (See also Standard 7.02, Forensic Assessments.)

2.02 Competence and Appropriate Use of Assessments and Interventions

(a) Psychologists who develop, administer, score, interpret, or use psychological assessment techniques, interviews, tests, or instruments do so in a manner and for purposes that are appropriate in light of the research on or evidence of the usefulness and proper application of the techniques.

(b) Psychologists refrain from misuse of assessment techniques, interventions, results, and interpretations and take reasonable steps to prevent others from misusing the information these techniques provide. This includes refraining from releasing raw test results or raw data to persons, other than to patients or clients as appropriate, who are not qualified to use such information. (See also Standards 1.02, Relationship of Ethics and Law, and 1.04, Boundaries of Competence.)

2.03 Test Construction

Psychologists who develop and conduct research with tests and other assessment techniques use scientific procedures and current professional knowledge for test design, standardization, validation, reduction or elimination of bias, and recommendations for use.

2.04 Use of Assessment in General and With Special Populations

(a) Psychologists who perform interventions or administer, score, interpret, or use assessment techniques are familiar with the reliability, validation, and related standardization or outcome studies of, and proper applications and uses of, the techniques they use.

(b) Psychologists recognize limits to the certainty with which diagnoses, judgments, or predictions can be made about individuals.

(c) Psychologists attempt to identify situations in which particular interventions or assessment techniques or norms may not be applicable or may require adjustment in administration or interpretation because of factors such as individuals' gender, age, race, ethnicity, national origin, religion, sexual orientation, disability, language, or socioeconomic status.

2.05 Interpreting Assessment Results

When interpreting assessment results, including automated interpretations, psychologists take into account the various test factors and characteristics of the person being assessed that might affect psychologists' judgments or reduce the accuracy of their interpretations. They indicate any significant reservations they have about the accuracy or limitations of their interpretations.

2.06 Unqualified Persons

Psychologists do not promote the use of psychological assessment techniques by unqualified persons. (See also Standard 1.22, Delegation to and Supervision of Subordinates.)

2.07 Obsolete Tests and Outdated Test Results

(a) Psychologists do not base their assessment or intervention decisions or recommendations on data or test results that are outdated for the current purpose.

(b) Similarly, psychologists do not base such decisions or recommendations on tests and measures that are obsolete and not useful for the current purpose.

2.08 Test Scoring and Interpretation Services

(a) Psychologists who offer assessment or scoring procedures to other professionals accurately describe the purpose, norms, validity, reliability, and applications of the

procedures and any special qualifications applicable to their use.

(b) Psychologists select scoring and interpretation services (including automated services) on the basis of evidence of the validity of the program and procedures as well as on other appropriate considerations.

(c) Psychologists retain appropriate responsibility for the appropriate application, interpretation, and use of assessment instruments, whether they score and interpret such tests themselves or use automated or other services.

2.09 Explaining Assessment Results

Unless the nature of the relationship is clearly explained to the person being assessed in advance and precludes provision of an explanation of results (such as in some organizational consulting, preemployment or security screenings, and forensic evaluations), psychologists ensure that an explanation of the results is provided using language that is reasonably understandable to the person assessed or to another legally authorized person on behalf of the client. Regardless of whether the scoring and interpretation are done by the psychologist, by assistants, or by automated or other outside services, psychologists take reasonable steps to ensure that appropriate explanations of results are given.

2.10 Maintaining Test Security

Psychologists make reasonable efforts to maintain the integrity and security of tests and other assessment techniques consistent with law, contractual obligations, and in a manner that permits compliance with the requirements of this Ethics Code. (See also Standard 1.02, Relationship of Ethics and Law.)

3. Advertising and Other Public Statements

3.01 Definition of Public Statements

Psychologists comply with this Ethics Code in public statements relating to their professional services, products, or publications or to the field of psychology. Public statements include but are not limited to paid or unpaid advertising, brochures, printed matter, directory listings, personal resumes or curricula vitae, interviews or comments for use in media, statements in legal proceedings, lectures and public oral presentations, and published materials.

3.02 Statements by Others

(a) Psychologists who engage others to create or place public statements that promote their professional practice, products, or activities retain professional responsibility for such statements.

(b) In addition, psychologists make reasonable efforts to prevent others whom they do not control (such as employers, publishers, sponsors, organizational clients, and representatives of the print or broadcast media) from making deceptive statements concerning psychologists' practice or professional or scientific activities.

(c) If psychologists learn of deceptive statements about their work made by others, psychologists make reasonable efforts to correct such statements.

(d) Psychologists do not compensate employees of press, radio, television, or other communication media in return for publicity in a news item.

(e) A paid advertisement relating to the psychologist's activities must be identified as such, unless it is already apparent from the context.

3.03 Avoidance of False or Deceptive Statements

(a) Psychologists do not make public statements that are false, deceptive, misleading, or fraudulent, either because of what they state, convey, or suggest or because of what they omit, concerning their research, practice, or other work activities or those of persons or organizations with which they are affiliated. As examples (and not in limitation) of this standard, psychologists do not make false or deceptive statements concerning (1) their training, experience, or competence; (2) their academic degrees; (3) their credentials; (4) their institutional or association affiliations; (5) their services; (6) the scientific or clinical basis for, or results or degree of success of, their services; (7) their fees; or (8) their publications or research findings. (See also Standards 6.15, Deception in Research, and 6.18, Providing Participants With Information About the Study.)

(b) Psychologists claim as credentials for their psychological work, only degrees that (1) were earned from a regionally accredited educational institution or (2) were the basis for psychology licensure by the state in which they practice.

3.04 Media Presentations

When psychologists provide advice or comment by means of public lectures, demonstrations, radio or television programs, prerecorded tapes, printed articles, mailed material, or other media, they take reasonable precautions to ensure that (1) the statements are based on appropriate psychological literature and practice, (2) the statements are otherwise consistent with this Ethics Code, and (3) the recipients of the information are not encouraged to infer that a relationship has been established with them personally.

3.05 Testimonials

Psychologists do not solicit testimonials from current psychotherapy clients or patients or other persons who because of their particular circumstances are vulnerable to undue influence.

3.06 In-Person Solicitation

Psychologists do not engage, directly or through agents, in uninvited in-person solicitation of business from actual or potential psychotherapy patients or clients or other persons who because of their particular circumstances are vulnerable to undue influence. However, this does not preclude attempt-

ing to implement appropriate collateral contacts with significant others for the purpose of benefiting an already engaged therapy patient.

4. Therapy

4.01 Structuring the Relationship

(a) Psychologists discuss with clients or patients as early as is feasible in the therapeutic relationship appropriate issues, such as the nature and anticipated course of therapy, fees, and confidentiality. (See also Standards 1.25, Fees and Financial Arrangements, and 5.01, Discussing the Limits of Confidentiality.)

(b) When the psychologist's work with clients or patients will be supervised, the above discussion includes that fact, and the name of the supervisor, when the supervisor has legal responsibility for the case.

(c) When the therapist is a student intern, the client or patient is informed of that fact.

(d) Psychologists make reasonable efforts to answer patients' questions and to avoid apparent misunderstandings about therapy. Whenever possible, psychologists provide oral and/or written information, using language that is reasonably understandable to the patient or client.

4.02 Informed Consent to Therapy

(a) Psychologists obtain appropriate informed consent to therapy or related procedures, using language that is reasonably understandable to participants. The content of informed consent will vary depending on many circumstances; however, informed consent generally implies that the person (1) has the capacity to consent, (2) has been informed of significant information concerning the procedure, (3) has freely and without undue influence expressed consent, and (4) consent has been appropriately documented.

(b) When persons are legally incapable of giving informed consent, psychologists obtain informed permission from a legally authorized person, if such substitute consent is permitted by law.

(c) In addition, psychologists (1) inform those persons who are legally incapable of giving informed consent about the proposed interventions in a manner commensurate with the persons' psychological capacities, (2) seek their assent to those interventions, and (3) consider such persons' preferences and best interests.

4.03 Couple and Family Relationships

(a) When a psychologist agrees to provide services to several persons who have a relationship (such as husband and wife or parents and children), the psychologist attempts to clarify at the outset (1) which of the individuals are patients or clients and (2) the relationship the psychologist will have with each person. This clarification includes the role of the psychologist and the probable uses of the services provided or the information obtained. (See also Standard 5.01, Discussing the Limits of Confidentiality.)

(b) As soon as it becomes apparent that the psychologist may be called on to perform potentially conflicting roles (such as marital counselor to husband and wife, and then witness for one party in a divorce proceeding), the psychologist attempts to clarify and adjust, or withdraw from, roles appropriately. (See also Standard 7.03, Clarification of Role, under Forensic Activities.)

4.04 Providing Mental Health Services to Those Served by Others

In deciding whether to offer or provide services to those already receiving mental health services elsewhere, psychologists carefully consider the treatment issues and the potential patient's or client's welfare. The psychologist discusses these issues with the patient or client, or another legally authorized person on behalf of the client, in order to minimize the risk of confusion and conflict, consults with the other service providers when appropriate, and proceeds with caution and sensitivity to the therapeutic issues.

4.05 Sexual Intimacies With Current Patients or Clients

Psychologists do not engage in sexual intimacies with current patients or clients.

4.06 Therapy With Former Sexual Partners

Psychologists do not accept as therapy patients or clients persons with whom they have engaged in sexual intimacies.

4.07 Sexual Intimacies With Former Therapy Patients

(a) Psychologists do not engage in sexual intimacies with a former therapy patient or client for at least two years after cessation or termination of professional services.

(b) Because sexual intimacies with a former therapy patient or client are so frequently harmful to the patient or client, and because such intimacies undermine public confidence in the psychology profession and thereby deter the public's use of needed services, psychologists do not engage in sexual intimacies with former therapy patients and clients even after a two-year interval except in the most unusual circumstances. The psychologist who engages in such activity after the two years following cessation or termination of treatment bears the burden of demonstrating that there has been no exploitation, in light of all relevant factors, including (1) the amount of time that has passed since therapy terminated, (2) the nature and duration of the therapy, (3) the circumstances of termination, (4) the patient's or client's personal history, (5) the patient's or client's current mental status, (6) the likelihood of adverse impact on the patient or client and others, and (7) any statements or actions made by the therapist during the course of therapy suggesting or inviting the possibility of a posttermination sexual or romantic relationship with the patient or client. (See also Standard 1.17, Multiple Relationships.)

4.08 Interruption of Services

(a) Psychologists make reasonable efforts to plan for facilitating care in the event that psychological services are interrupted by factors such as the psychologist's illness, death, unavailability, or relocation or by the client's relocation or financial limitations. (See also Standard 5.09, Preserving Records and Data.)

(b) When entering into employment or contractual relationships, psychologists provide for orderly and appropriate resolution of responsibility for patient or client care in the event that the employment or contractual relationship ends, with paramount consideration given to the welfare of the patient or client.

4.09 Terminating the Professional Relationship

(a) Psychologists do not abandon patients or clients. (See also Standard 1.25e, under Fees and Financial Arrangements.)

(b) Psychologists terminate a professional relationship when it becomes reasonably clear that the patient or client no longer needs the service, is not benefiting, or is being harmed by continued service.

(c) Prior to termination for whatever reason, except where precluded by the patient's or client's conduct, the psychologist discusses the patient's or client's views and needs, provides appropriate pretermination counseling, suggests alternative service providers as appropriate, and takes other reasonable steps to facilitate transfer of responsibility to another provider if the patient or client needs one immediately.

5. Privacy and Confidentiality

These Standards are potentially applicable to the professional and scientific activities of all psychologists.

5.01 Discussing the Limits of Confidentiality

(a) Psychologists discuss with persons and organizations with whom they establish a scientific or professional relationship (including, to the extent feasible, minors and their legal representatives) (1) the relevant limitations on confidentiality, including limitations where applicable in group, marital, and family therapy or in organizational consulting, and (2) the foreseeable uses of the information generated through their services.

(b) Unless it is not feasible or is contraindicated, the discussion of confidentiality occurs at the outset of the relationship and thereafter as new circumstances may warrant.

(c) Permission for electronic recording of interviews is secured from clients and patients.

5.02 Maintaining Confidentiality

Psychologists have a primary obligation and take reasonable precautions to respect the confidentiality rights of those with whom they work or consult, recognizing that confidentiality may be established by law, institutional rules, or professional or scientific relationships. (See also Standard 6.26, Professional Reviewers.)

5.03 Minimizing Intrusions on Privacy

(a) In order to minimize intrusions on privacy, psychologists include in written and oral reports, consultations, and the like, only information germane to the purpose for which the communication is made.

(b) Psychologists discuss confidential information obtained in clinical or consulting relationships, or evaluative data concerning patients, individual or organizational clients, students, research participants, supervisees, and employees, only for appropriate scientific or professional purposes and only with persons clearly concerned with such matters.

5.04 Maintenance of Records

Psychologists maintain appropriate confidentiality in creating, storing, accessing, transferring, and disposing of records under their control, whether these are written, automated, or in any other medium. Psychologists maintain and dispose of records in accordance with law and in a manner that permits compliance with the requirements of this Ethics Code.

5.05 Disclosures

(a) Psychologists disclose confidential information without the consent of the individual only as mandated by law, or where permitted by law for a valid purpose, such as (1) to provide needed professional services to the patient or the individual or organizational client, (2) to obtain appropriate professional consultations, (3) to protect the patient or client or others from harm, or (4) to obtain payment for services, in which instance disclosure is limited to the minimum that is necessary to achieve the purpose.

(b) Psychologists also may disclose confidential information with the appropriate consent of the patient or the individual or organizational client (or of another legally authorized person on behalf of the patient or client), unless prohibited by law.

5.06 Consultations

When consulting with colleagues, (1) psychologists do not share confidential information that reasonably could lead to the identification of a patient, client, research participant, or other person or organization with whom they have a confidential relationship unless they have obtained the prior consent of the person or organization or the disclosure cannot be avoided, and (2) they share information only to the extent necessary to achieve the purposes of the consultation. (See also Standard 5.02, Maintaining Confidentiality.)

5.07 Confidential Information in Databases

(a) If confidential information concerning recipients of psychological services is to be entered into databases or systems of records available to persons whose access has not been consented to by the recipient, then psychologists use coding or other techniques to avoid the inclusion of personal identifiers.

(b) If a research protocol approved by an institutional review board or similar body requires the inclusion of personal identifiers, such identifiers are deleted before the information is made accessible to persons other than those of whom the subject was advised.

(c) If such deletion is not feasible, then before psychologists transfer such data to others or review such data collected by others, they take reasonable steps to determine that appropriate consent of personally identifiable individuals has been obtained.

5.08 Use of Confidential Information for Didactic or Other Purposes

(a) Psychologists do not disclose in their writings, lectures, or other public media, confidential, personally identifiable information concerning their patients, individual or organizational clients, students, research participants, or other recipients of their services that they obtained during the course of their work, unless the person or organization has consented in writing or unless there is other ethical or legal authorization for doing so.

(b) Ordinarily, in such scientific and professional presentations, psychologists disguise confidential information concerning such persons or organizations so that they are not individually identifiable to others and so that discussions do not cause harm to subjects who might identify themselves.

5.09 Preserving Records and Data

A psychologist makes plans in advance so that confidentiality of records and data is protected in the event of the psychologist's death, incapacity, or withdrawal from the position or practice.

5.10 Ownership of Records and Data

Recognizing that ownership of records and data is governed by legal principles, psychologists take reasonable and lawful steps so that records and data remain available to the extent needed to serve the best interests of patients, individual or organizational clients, research participants, or appropriate others.

5.11 Withholding Records for Nonpayment

Psychologists may not withhold records under their control that are requested and imminently needed for a patient's or client's treatment solely because payment has not been received, except as otherwise provided by law.

6. Teaching, Training Supervision, Research, and Publishing

6.01 Design of Education and Training Programs

Psychologists who are responsible for education and training programs seek to ensure that the programs are competently designed, provide the proper experiences, and meet the requirements for licensure, certification, or other goals for which claims are made by the program.

6.02 Descriptions of Education and Training Programs

(a) Psychologists responsible for education and training programs seek to ensure that there is a current and accurate description of the program content, training goals and objectives, and requirements that must be met for satisfactory completion of the program. This information must be made readily available to all interested parties.

(b) Psychologists seek to ensure that statements concerning their course outlines are accurate and not misleading, particularly regarding the subject matter to be covered, bases for evaluating progress, and the nature of course experiences. (See also Standard 3.03, Avoidance of False or Deceptive Statements.)

(c) To the degree to which they exercise control, psychologists responsible for announcements, catalogs, brochures, or advertisements describing workshops, seminars, or other non-degree-granting educational programs ensure that they accurately describe the audience for which the program is intended, the educational objectives, the presenters, and the fees involved.

6.03 Accuracy and Objectivity in Teaching

(a) When engaged in teaching or training, psychologists present psychological information accurately and with a reasonable degree of objectivity.

(b) When engaged in teaching or training, psychologists recognize the power they hold over students or supervisees and therefore make reasonable efforts to avoid engaging in conduct that is personally demeaning to students or supervisees. (See also Standards 1.09, Respecting Others, and 1.12, Other Harassment.)

6.04 Limitation on Teaching

Psychologists do not teach the use of techniques or procedures that require specialized training, licensure, or expertise, including but not limited to hypnosis, biofeedback, and projective techniques, to individuals who lack the prerequisite training, legal scope of practice, or expertise.

6.05 Assessing Student and Supervisee Performance

(a) In academic and supervisory relationships, psychologists establish an appropriate process for providing feedback to students and supervisees.

(b) Psychologists evaluate students and supervisees on the basis of their actual performance on relevant and established program requirements.

6.06 Planning Research

(a) Psychologists design, conduct, and report research in accordance with recognized standards of scientific competence and ethical research.

(b) Psychologists plan their research so as to minimize the possibility that results will be misleading.

(c) In planning research, psychologists consider its ethical acceptability under the Ethics Code. If an ethical issue is unclear, psychologists seek to resolve the issue through consultation with institutional review boards, animal care and use committees, peer consultations, or other proper mechanisms.

(d) Psychologists take reasonable steps to implement appropriate protections for the rights and welfare of human participants, other persons affected by the research, and the welfare of animal subjects.

6.07 Responsibility

(a) Psychologists conduct research competently and with due concern for the dignity and welfare of the participants.

(b) Psychologists are responsible for the ethical conduct of research conducted by them or by others under their supervision or control.

(c) Researchers and assistants are permitted to perform only those tasks for which they are appropriately trained and prepared.

(d) As part of the process of development and implementation of research projects, psychologists consult those with expertise concerning any special population under investigation or most likely to be affected.

6.08 Compliance With Law and Standards

Psychologists plan and conduct research in a manner consistent with federal and state law and regulations, as well as professional standards governing the conduct of research, and particularly those standards governing research with human participants and animal subjects.

6.09 Institutional Approval

Psychologists obtain from host institutions or organizations appropriate approval prior to conducting research, and they provide accurate information about their research proposals. They conduct the research in accordance with the approved research protocol.

6.10 Research Responsibilities

Prior to conducting research (except research involving only anonymous surveys, naturalistic observations, or similar research), psychologists enter into an agreement with participants that clarifies the nature of the research and the responsibilities of each party.

6.11 Informed Consent to Research

(a) Psychologists use language that is reasonably understandable to research participants in obtaining their appropriate informed consent (except as provided in Standard 6.12, Dispensing With Informed Consent). Such informed consent is appropriately documented.

(b) Using language that is reasonably understandable to participants, psychologists inform participants of the nature of the research; they inform participants that they are free to participate or to decline to participate or to withdraw from the research; they explain the foreseeable consequences of declining or withdrawing; they inform participants of significant factors that may be expected to influence their willingness to participate (such as risks, discomfort, adverse effects, or limitations on confidentiality, except as provided in Standard 6.15, Deception in Research); and they explain other aspects about which the prospective participants inquire.

(c) When psychologists conduct research with individuals such as students or subordinates, psychologists take special care to protect the prospective participants from adverse consequences of declining or withdrawing from participation.

(d) When research participation is a course requirement or opportunity for extra credit, the prospective participant is given the choice of equitable alternative activities.

(e) For persons who are legally incapable of giving informed consent, psychologists nevertheless (1) provide an appropriate explanation, (2) obtain the participant's assent, and (3) obtain appropriate permission from a legally authorized person, if such substitute consent is permitted by law.

6.12 Dispensing With Informed Consent

Before determining that planned research (such as research involving only anonymous questionnaires, naturalistic observations, or certain kinds of archival research) does not require the informed consent of research participants, psychologists consider applicable regulations and institutional review board requirements, and they consult with colleagues as appropriate.

6.13 Informed Consent in Research Filming or Recording

Psychologists obtain informed consent from research participants prior to filming or recording them in any form, unless the research involves simply naturalistic observations in public places and it is not anticipated that the recording will be used in a manner that could cause personal identification or harm.

6.14 Offering Inducements for Research Participants

(a) In offering professional services as an inducement to obtain research participants, psychologists make clear the nature of the services, as well as the risks, obligations, and

limitations. (See also Standard 1.18, Barter [With Patients or Clients].)

(b) Psychologists do not offer excessive or inappropriate financial or other inducements to obtain research participants, particularly when it might tend to coerce participation.

6.15 Deception in Research

(a) Psychologists do not conduct a study involving deception unless they have determined that the use of deceptive techniques is justified by the study's prospective scientific, educational, or applied value and that equally effective alternative procedures that do not use deception are not feasible.

(b) Psychologists never deceive research participants about significant aspects that would affect their willingness to participate, such as physical risks, discomfort, or unpleasant emotional experiences.

(c) Any other deception that is an integral feature of the design and conduct of an experiment must be explained to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the research. (See also Standard 6.18, Providing Participants With Information About the Study.)

6.16 Sharing and Utilizing Data

Psychologists inform research participants of their anticipated sharing or further use of personally identifiable research data and of the possibility of unanticipated future uses.

6.17 Minimizing Invasiveness

In conducting research, psychologists interfere with the participants or milieu from which data are collected only in a manner that is warranted by an appropriate research design and that is consistent with psychologists' roles as scientific investigators.

6.18 Providing Participants With Information About the Study

(a) Psychologists provide a prompt opportunity for participants to obtain appropriate information about the nature, results, and conclusions of the research, and psychologists attempt to correct any misconceptions that participants may have.

(b) If scientific or humane values justify delaying or withholding this information, psychologists take reasonable measures to reduce the risk of harm.

6.19 Honoring Commitments

Psychologists take reasonable measures to honor all commitments they have made to research participants.

6.20 Care and Use of Animals in Research

(a) Psychologists who conduct research involving animals treat them humanely.

(b) Psychologists acquire, care for, use, and dispose of animals in compliance with current federal, state, and local laws and regulations, and with professional standards.

(c) Psychologists trained in research methods and experienced in the care of laboratory animals supervise all procedures involving animals and are responsible for ensuring appropriate consideration of their comfort, health, and humane treatment.

(d) Psychologists ensure that all individuals using animals under their supervision have received instruction in research methods and in the care, maintenance, and handling of the species being used, to the extent appropriate to their role.

(e) Responsibilities and activities of individuals assisting in a research project are consistent with their respective competencies.

(f) Psychologists make reasonable efforts to minimize the discomfort, infection, illness, and pain of animal subjects.

(g) A procedure subjecting animals to pain, stress, or privation is used only when an alternative procedure is unavailable and the goal is justified by its prospective scientific, educational, or applied value.

(h) Surgical procedures are performed under appropriate anesthesia; techniques to avoid infection and minimize pain are followed during and after surgery.

(i) When it is appropriate that the animal's life be terminated, it is done rapidly, with an effort to minimize pain, and in accordance with accepted procedures.

6.21 Reporting of Results

(a) Psychologists do not fabricate data or falsify results in their publications.

(b) If psychologists discover significant errors in their published data, they take reasonable steps to correct such errors in a correction, retraction, erratum, or other appropriate publication means.

6.22 Plagiarism

Psychologists do not present substantial portions or elements of another's work or data as their own, even if the other work or data source is cited occasionally.

6.23 Publication Credit

(a) Psychologists take responsibility and credit, including authorship credit, only for work they have actually performed or to which they have contributed.

(b) Principal authorship and other publication credits accurately reflect the relative scientific or professional contributions of the individuals involved, regardless of their relative status. Mere possession of an institutional position, such as Department Chair, does not justify authorship credit. Minor contributions to the research or to the writing for publications are appropriately acknowledged, such as in footnotes or in an introductory statement.

(c) A student is usually listed as principal author on any multiple-authored article that is substantially based on the student's dissertation or thesis.

6.24 Duplicate Publication of Data

Psychologists do not publish, as original data, data that have been previously published. This does not preclude republishing data when they are accompanied by proper acknowledgment.

6.25 Sharing Data

After research results are published, psychologists do not withhold the data on which their conclusions are based from other competent professionals who seek to verify the substantive claims through reanalysis and who intend to use such data only for that purpose, provided that the confidentiality of the participants can be protected and unless legal rights concerning proprietary data preclude their release.

6.26 Professional Reviewers

Psychologists who review material submitted for publication, grant, or other research proposal review respect the confidentiality of and the proprietary rights in such information of those who submitted it.

7. Forensic Activities

7.01 Professionalism

Psychologists who perform forensic functions, such as assessments, interviews, consultations, reports, or expert testimony, must comply with all other provisions of this Ethics Code to the extent that they apply to such activities. In addition, psychologists base their forensic work on appropriate knowledge of and competence in the areas underlying such work, including specialized knowledge concerning special populations. (See also Standards 1.06, Basis for Scientific and Professional Judgments; 1.08, Human Differences; 1.15, Misuse of Psychologists' Influence; and 1.23, Documentation of Professional and Scientific Work.)

7.02 Forensic Assessments

(a) Psychologists' forensic assessments, recommendations, and reports are based on information and techniques (including personal interviews of the individual, when appropriate) sufficient to provide appropriate substantiation for their findings. (See also Standards 1.03, Professional and Scientific Relationship; 1.23, Documentation of Professional and Scientific Work; 2.01, Evaluation, Diagnosis, and Interventions in Professional Context; and 2.05, Interpreting Assessment Results.)

(b) Except as noted in (c), below, psychologists provide written or oral forensic reports or testimony of the psychological characteristics of an individual only after they have conducted an examination of the individual adequate to support their statements or conclusions.

(c) When, despite reasonable efforts, such an examination is not feasible, psychologists clarify the impact of their limited information on the reliability and validity of their reports and testimony, and they appropriately limit the nature and extent of their conclusions or recommendations.

7.03 Clarification of Role

In most circumstances, psychologists avoid performing multiple and potentially conflicting roles in forensic matters. When psychologists may be called on to serve in more than one role in a legal proceeding—for example, as consultant or expert for one party or for the court and as a fact witness—they clarify role expectations and the extent of confidentiality in advance to the extent feasible, and thereafter as changes occur, in order to avoid compromising their professional judgment and objectivity and in order to avoid misleading others regarding their role.

7.04 Truthfulness and Candor

(a) In forensic testimony and reports, psychologists testify truthfully, honestly, and candidly and, consistent with applicable legal procedures, describe fairly the bases for their testimony and conclusions.

(b) Whenever necessary to avoid misleading, psychologists acknowledge the limits of their data or conclusions.

7.05 Prior Relationships

A prior professional relationship with a party does not preclude psychologists from testifying as fact witnesses or from testifying to their services to the extent permitted by applicable law. Psychologists appropriately take into account ways in which the prior relationship might affect their professional objectivity or opinions and disclose the potential conflict to the relevant parties.

7.06 Compliance With Law and Rules

In performing forensic roles, psychologists are reasonably familiar with the rules governing their roles. Psychologists are aware of the occasionally competing demands placed upon them by these principles and the requirements of the court system, and attempt to resolve these conflicts by making known their commitment to this Ethics Code and taking steps to resolve the conflict in a responsible manner. (See also Standard 1.02, Relationship of Ethics and Law.)

8. Resolving Ethical Issues

8.01 Familiarity With Ethics Code

Psychologists have an obligation to be familiar with this Ethics Code, other applicable ethics codes, and their application to psychologists' work. Lack of awareness or misunderstanding of an ethical standard is not itself a defense to a charge of unethical conduct.

8.02 Confronting Ethical Issues

When a psychologist is uncertain whether a particular situation or course of action would violate this Ethics Code, the psychologist ordinarily consults with other psychologists knowledgeable about ethical issues, with state or national

psychology ethics committees, or with other appropriate authorities in order to choose a proper response.

8.03 Conflicts Between Ethics and Organizational Demands

If the demands of an organization with which psychologists are affiliated conflict with this Ethics Code, psychologists clarify the nature of the conflict, make known their commitment to the Ethics Code, and to the extent feasible, seek to resolve the conflict in a way that permits the fullest adherence to the Ethics Code.

8.04 Informal Resolution of Ethical Violations

When psychologists believe that there may have been an ethical violation by another psychologist, they attempt to resolve the issue by bringing it to the attention of that individual if an informal resolution appears appropriate and the intervention does not violate any confidentiality rights that may be involved.

8.05 Reporting Ethical Violations

If an apparent ethical violation is not appropriate for informal resolution under Standard 8.04 or is not resolved properly in that fashion, psychologists take further action appropriate to the situation, unless such action conflicts with confidentiality rights in ways that cannot be resolved. Such action might include referral to state or national committees on professional ethics or to state licensing boards.

8.06 Cooperating With Ethics Committees

Psychologists cooperate in ethics investigations, proceedings, and resulting requirements of the APA or any affiliated state psychological association to which they belong. In doing so, they make reasonable efforts to resolve any issues as to confidentiality. Failure to cooperate is itself an ethics violation.

8.07 Improper Complaints

Psychologists do not file or encourage the filing of ethics complaints that are frivolous and are intended to harm the respondent rather than to protect the public.

UNIVERSITY OF GUAM
UNIBETSEDÅT GUAHAN
COMMITTEE on HUMAN RESEARCH SUBJECTS

Office of the GRADUATE SCHOOL and RESEARCH
UOG Station, Mangilao, GU 96923

TO: Principal Investigators/Researchers at UOG

FROM: UOG Committee on Human Research Subjects (CHRS)

SUBJECT: Institutional Review Assuring Human Rights of Subjects

This memo **describes policy and review criteria** for the protection of human subjects involved in projects conducted at, sponsored by, or affiliated with the University of Guam, regardless of the absence or presence of support, and regardless of who else may have reviewed them. Research projects (whether professional or student) that obtain (a) data through interaction with individuals, or (b) identifiable private information are subject to review. All such projects must receive prior exemption or approval from the CHRS, which serves as the University's Institutional Review Board in compliance with federal policy established by the U.S. Office of Science and Technology. Your understanding of these regulations is important for the University's adherence to federal policy on this topic, and for your own liability assumed in the performance of research and training projects.

Each of these **federal departments and agencies** have adopted these regulations for the protection of human subjects involved in research conducted or funded by the following:

US Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Consumer Product Safety Commission; International Development Cooperation Agency; Agency for International Development; Department of Housing and Urban Development; Department of Justice; Department of Defense; Department of Education; Department of Veteran Affairs; Environmental Protection Agency; National Science Foundation; Department of Health and Human Services; Department of Transportation.

Researchers should be aware of other regional review boards in addition to the University CHRS. The Guam Memorial Hospital has an IRB for medical research on Guam. Also, permit reviews are required by the Federated States of Micronesia, with similar legislation being considered by other Pacific Island entities. The FSM has an established clearinghouse procedure for anyone proposing research in the areas of archaeology, oral history, social culture, custom, arts/crafts, archival, political history, or anything to do with historic and cultural resources in the FSM.

To what does this policy apply?

University policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States. Research that is neither conducted nor supported by a federal department or agency but is subject to regulation must be reviewed and approved by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

Unless otherwise required, research activities where the only involvement of human subjects will be in one or more of the following categories may be exempted or subjected only to expedited review procedures as assessed from the CHRS Review Application:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures or observation of public behavior, unless: (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research not exempt under paragraph 2 of this section, if: (i) subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are designed to study, evaluate or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs; or (iv) possible changes in methods, payment or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the USDA.

Section 103 Assuring compliance with this policy--research conducted or supported by any federal department or agency.

(a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, appropriate for the research in question, on file with the Office for Protection from Research Risks, HHS, and approved for federal wide use by that office.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided by this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

> (1) A statement of principals governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation.
>
> (2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and record keeping duties.
>
> (3) A list of IRB members identified by name; earned degrees; representative capacity; . . . . sufficient to describe each members chief anticipated contributions . . .
>
> (4) Written procedures which the IRB will follow . . .
>
> (5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and (ii) any suspension or termination of IRB approval.

(c) to (g) [additional specifications and policy for assurances]

(f) . . . Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the

Section 102 Definitions

(a) *Department or agency head* . . .

(b) *Institution* . . .

(c) *Legally authorized representative* . . .

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. . . .

(e) *Research subject to regulation*, . . . encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity. It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (e.g., Wage and Hour requirements administered by the Department of Labor).

(f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. (*intervention* and *private information* are given expanded definition)

(g) *IRB* . . .

(h) *IRB approval* . . .

(i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) *Certification* means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

(b) Unless otherwise required . . . research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures or observation of public behavior, unless: (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research [under 101(b)(2)] that is not exempt under paragraph (b)(2) of this section, if: (i) ... subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects ... which are designed to study, evaluate or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs ...(iv) possible changes in methods or ... payment ... or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the USDA.

UNIVERSITY OF GUAM
UNIBETSEDAT GUAHAN
COMMITTEE on HUMAN RESEARCH SUBJECTS
RESEARCH COUNCIL
GRADUATE SCHOOL & RESEARCH
UOG Station, Mangilao, GU 96923

Summary of Federal Policy for the Protection of Human Subjects; Notices and Rules

SOURCE: Federal Register, June 18, 1991 (Regulations effective August 19, 1991)

"This document sets forth a common **Federal Policy** for the Protection of Human Subjects accepted **by the Office of Science and Technology Policy** and promulgated in regulation by each of the listed Departments and Agencies."

Each of these Departments and Agencies have adopted the common rule as regulations for the protection of human subjects involved in research conducted or funded by the following:

US Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Consumer Product Safety Commission; International Development Cooperation Agency; Agency for International Development; Department of Housing and Urban Development; Department of Justice; Department of Defense; Department of Education; Department of Veteran Affairs; Environmental Protection Agency; National Science Foundation; Department of Health and Human Services; Department of Transportation.

(Quoted excerpts)

Section 101 To what does this policy apply?

(a) . . . this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. . . . It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) . . .
(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in Section 102(e) must be reviewed and approved, in compliance with Sections 101,102, and 107 through 117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

1.18 Barter (With Patients or Clients)

Psychologists ordinarily refrain from accepting goods, services, or other nonmonetary remuneration from patients or clients in return for psychological services because such arrangements create inherent potential for conflicts, exploitation, and distortion of the professional relationship. A psychologist may participate in bartering only if (1) it is not clinically contraindicated, and (2) the relationship is not exploitative. (See also Standards 1.17, Multiple Relationships, and 1.25, Fees and Financial Arrangements.)

1.19 Exploitative Relationships

(a) Psychologists do not exploit persons over whom they have supervisory, evaluative, or other authority such as students, supervisees, employees, research participants, and clients or patients. (See also Standards 4.05–4.07 regarding sexual involvement with clients or patients.)

(b) Psychologists do not engage in sexual relationships with students or supervisees in training over whom the psychologist has evaluative or direct authority, because such relationships are so likely to impair judgment or be exploitative.

1.20 Consultations and Referrals

(a) Psychologists arrange for appropriate consultations and referrals based principally on the best interests of their patients or clients, with appropriate consent, and subject to other relevant considerations, including applicable law and contractual obligations. (See also Standards 5.01, Discussing the Limits of Confidentiality, and 5.06, Consultations.)

(b) When indicated and professionally appropriate, psychologists cooperate with other professionals in order to serve their patients or clients effectively and appropriately.

(c) Psychologists' referral practices are consistent with law.

1.21 Third-Party Requests for Services

(a) When a psychologist agrees to provide services to a person or entity at the request of a third party, the psychologist clarifies to the extent feasible, at the outset of the service, the nature of the relationship with each party. This clarification includes the role of the psychologist (such as therapist, organizational consultant, diagnostician, or expert witness), the probable uses of the services provided or the information obtained, and the fact that there may be limits to confidentiality.

(b) If there is a foreseeable risk of the psychologist's being called upon to perform conflicting roles because of the involvement of a third party, the psychologist clarifies the nature and direction of his or her responsibilities, keeps all parties appropriately informed as matters develop, and resolves the situation in accordance with this Ethics Code.

1.22 Delegation to and Supervision of Subordinates

(a) Psychologists delegate to their employees, supervisees, and research assistants only those responsibilities that such persons can reasonably be expected to perform competently, on the basis of their education, training, or experience, either independently or with the level of supervision being provided.

(b) Psychologists provide proper training and supervision to their employees or supervisees and take reasonable steps to see that such persons perform services responsibly, competently, and ethically.

(c) If institutional policies, procedures, or practices prevent fulfillment of this obligation, psychologists attempt to modify their role or to correct the situation to the extent feasible.

1.23 Documentation of Professional and Scientific Work

(a) Psychologists appropriately document their professional and scientific work in order to facilitate provision of services later by them or by other professionals, to ensure accountability, and to meet other requirements of institutions or the law.

(b) When psychologists have reason to believe that records of their professional services will be used in legal proceedings involving recipients of or participants in their work, they have a responsibility to create and maintain documentation in the kind of detail and quality that would be consistent with reasonable scrutiny in an adjudicative forum. (See also Standard 7.01, Professionalism, under Forensic Activities.)

1.24 Records and Data

Psychologists create, maintain, disseminate, store, retain, and dispose of records and data relating to their research, practice, and other work in accordance with law and in a manner that permits compliance with the requirements of this Ethics Code. (See also Standard 5.04, Maintenance of Records.)

1.25 Fees and Financial Arrangements

(a) As early as is feasible in a professional or scientific relationship, the psychologist and the patient, client, or other appropriate recipient of psychological services reach an agreement specifying the compensation and the billing arrangements.

(b) Psychologists do not exploit recipients of services or payors with respect to fees.

(c) Psychologists' fee practices are consistent with law.

(d) Psychologists do not misrepresent their fees.

(e) If limitations to services can be anticipated because of limitations in financing, this is discussed with the patient, client, or other appropriate recipient of services as

certification is not submitted within these time limits, the application or proposal may be returned to the institution. (Approved by the Office of Management and Budget under Control Number 9999-0020.)

Sections 104 through 106 [Reserved]

Section 107 IRB membership.

a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women.

c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

e) No IRB may have a member participate in review of any project in which the member has a conflicting interest, except to provide information.

f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Section 108 IRB functions and operations.

Each IRB shall:

a) Follow written procedures;

b) Except when an expedited review procedure is used review proposed research at convened meetings at which a majority of the members of the IRB are present, including at lease one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

Section 109 IRB Review of Research.

a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities.

b) An IRB shall require that information given to subjects as part of informed consent is in accordance with Section.116. The IRB may require that information, in addition to that specifically mentioned in Section.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

c) An IRB shall require documentation of informed consent.

d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity.

e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

Section 110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

a) In the Federal Register, a list of categories of research that may be reviewed by the IRB through an expedited review procedure will be amended, as appropriate after consultation with other departments and agencies.

b) An IRB may use the expedited review procedure to review

1. Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk.

2. Minor changes in previously approved research.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson. Reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research.

Section 111 Criteria for IRB Approval.

a) To approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized.

2. Risks to subjects are reasonable in relation to anticipated benefits. The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized.

5. Informed consent will be appropriately documented.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Section 112 Additional Institutional Review.

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review by officials of the institution.

Section 113 Suspension or termination of IRB Approval.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

Section 114 Cooperative Research.

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

An institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

Section 115 IRB Records.

An IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

1. Copies of all research proposals reviewed.

2. Minutes of IRB meetings

3. Records of continuing review activities.

4. Copies of all correspondence.

5. A list of IRB members.

6. Written procedures for the IRB.

Section 116 General Requirements for Informed Consent.

An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.

a) Basic elements of informed consent

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

2. A description of any reasonably foreseeable risks or discomforts to the subject;

3. A description of any benefits to the subject or to others which may reasonably be expected from the research;

4. A disclosure of appropriate alternative procedures or courses of treatment, if any;

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6. An explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

7. An explanation of whom to contact for answers to pertinent questions;

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time.

b) When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks;

2. Anticipated circumstances under which the subject's participation may be terminated;

3. Any additional costs to the subject;

4. The consequences of a subject's decision to withdraw.

Section 117 Documentation of Informed Consent.

a) Informed consent shall be documented by the use of written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

b) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.

2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required.

Section 118 Applications and proposals lacking definite plans for involvement of human subjects.

Section 119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy.

Section 120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency

Section 121 [Reserved]

Section 122 Use of Federal funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

Section 123 Early termination of research support: Evaluation of applications and proposals.

a) The department or agency head may require that department or agency support for any project to be terminated or suspended when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

Section 124 Conditional IRB approval.

The department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary.

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Greetings to Senator Kasperbauer, members of the Committee On Education, and other attendees to today's Public Hearing. I speak on the subject of Bill 347 drawing from my experience of 20 years conducting research involving human subjects on Guam and in Micronesia, and my tenure with the University's Committee on Human Research Subjects since it's inception in 1982.

I strongly support the intent of Bill 347 that any research study involving the participation of citizens and residents of Guam should be required to have at least one review by an appropriately constituted institutional review board established on Guam

Scientific research has produced substantial social benefits, yet has also posed some troubling ethical questions. Since 1945, various codes for the proper and responsible conduct of human experimentation in medical research have been adopted. Basic principles of research involving human subjects developed by these codes have been summarized in the *Belmont Report*, by The National Commission for the Protection of Human Subjects of Biomedical & Behavioral Research, U.S. Department of Health, Education and Welfare (Published: April 18, 1979). I note this and attach a summary of it for you to clarify the ethical issues inherent in research involving human subjects. The essential heart of concern is

Respect for Persons: the idea that individuals are capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to a persons' considered opinions and choices. To show lack of respect for an autonomous agent is to deny an individual the freedom to act on those considered judgements, or to withhold information necessary to make a considered judgement Respect for persons demands that subjects enter into the research voluntarily and with adequate information.

Applications of the general principles to the conduct of research leads to consideration of the following requirements: *1. Informed Consent:* requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them, and *2. Assessment of Risks and Benefits:* presents both an opportunity and a responsibility. Many kinds of possible harms and benefits need to be taken into account. There are, for example, risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits. Risk can perhaps never be entirely eliminated, but it can often be reduced by careful attention to alternative procedures.

The University of Guam's Human Research Subjects Committee, an irb meeting the appropriate federal guidelines, has more than adequately carried out this responsibility for research involving or associated with UOG faculty or students. I have attached a copy of their guidelines to investigators. In recent years and with the assistance of UOG faculty the Guam Memorial Hospital has established a similar irb for research within its facility, or in association with its personnel and medical staff. The purpose is to comply with federal regulation for grant funding:

SOURCE: Federal Register, June 18, 1991 (Regulations effective August 19, 1991) **Section 103 Assuring compliance with this policy--research conducted or supported by any federal department or agency.** (a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency

head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, appropriate for the research in question, on file with the Office for Protection from Research Risks, HHS, and approved for federal wide use by that office.

Through this federal mandate, the UOG HRSC has become involved with numerous research projects conducted on-island by other universities and research institutions from off-island. I have attached a summary for your clarification. As this federal policy dictates:

SOURCE: Federal Register, June 18, 1991 (Regulations effective August 19, 1991) **Section 114 Cooperative Research.** Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. An institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

Unfortunately, this is not required for the island territory of Guam, rather it only becomes mandated between institutions. Thus it is possible for federally funded research projects from off-island institutions, to go through or affiliate with a Guam institution not covered by its own irb and separate from UOG or GMH (e.g., a private medical clinic, Naval Hospital, or DPHSS, MHSA, DPR, etc.) AND THEY CAN CHOOSE NOT TO HAVE A GUAM BASED IRB REVIEW.

Yet, the UOG CHRS, a Guam based irb, is very capable of handling these few occassional cases which may arise in any given year, and has the developed organizational mechanisms to efficiently and effectively process such cases. The UOG CHRS can fully achieve the intent of Bill 347, minimize and avoid any delay or obstruction that could adversely affect such research projects, and do this in a cost effective manner because it would fit within their normal processing of on-island research studies. The UOG CHRS handles about 25-30 studies each year, most of these being Expedited/low risk studies by graduate and undergraduate students, with 3-4 major studies involving UOG faculty affiliated with local agencies (e.g., DPHSS, MHSA, etc.).

The UOG CHRS is experienced and can provide an on-island irb review service to any agency, private entity, or off-island institution that does not have its own or other access to a Guam based irb. This is based on the idea that the legislative intent is to mandate that any research study involving human subjects has at least one on-island review. If that is the intent, then Guam has a ready mechanism in the form of the UOG CHRS to ensure that all of the following federal requirements are satisfied by any research covered by this law:

1. Risks to subjects are minimized.
2. Risks to subjects are reasonable in relation to anticipated benefits.
3. Selection of subjects is equitable.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized .
5. Informed consent will be appropriately documented.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

However, as currently written, Bill 347 establishes an unnecessary additional island-wide IRB. Moreover, it includes a section 24102. ***Board; Terms; Appointment; Continuance; Removal.*** which is a confusing listing of membership, and does not fit the federal guidelines for irb structure. For example, why only include the Director of DPHSS or his/her designee, and not the director of MHSA, DDPR, DOE, or the new agency for disabilities; and why is it so heavily weighted with people having no expertise in research or any academic science? What is the purpose of including an odd assemblage of persons – who may not have the skill and knowledge for reviewing technical methodologies to ensure informed consent and procedures to handle any risks involved? Within the federal policy for irb's it states:

SOURCE: Federal Register, June 18, 1991 (Regulations effective August 19, 1991) **Section 107 IRB membership.**

a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women.

c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

e) No IRB may have a member participate in review of any project in which the member has a conflicting interest, except to provide information.

f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

I recommend the following changes be made to Bill No. 347

In Section 1. Legislative Findings

Replace the second sentence on lines 7-10 which reads: "It further finds that the creation of a review board is the appropriate body to review proposals, plans, procedures and protocols for research involving human subjects and to approve or disapprove the same."

With: "It further finds that ***there are institutional review boards on Guam which conform to federal guidelines for such entities which are*** the appropriate bodies to review proposals, plans, procedures and protocols for research involving human subjects and to approve or disapprove the same."

Insert into the second paragraph on lines 11-15 an additional condition confronting Guam, so it reads:

"Further more, the legislature finds that ***on occassions*** human research conducted on Guam does not always acquire informed consent from persons participating in the programs, ***that some research although having obtained off-island irb reveiws fail to take into consideration unique island cultural and social conditions that confound or negate an individual's ability to make a considered judgement about his/her participation*** , and that there is a need to regulate and mandate informed consent to ensure that those persons participating are adequately informed."

Replace the third paragraph lines 16-18 to read:

"In the case where an investigator, entity, or agency engaged in research subject to regulation does not have nor is affiliated with an appropriately constituted institutional review board on Guam so they can conform to the requirements of this law, the University of Guam's institutional review board will provide an appropriate review for the purposes of this law."

This makes apparent the need to change the title of the law to be:

AN ACT TO ADD CHAPTER 24, DIVISION 3, 17 GCA TO REQUIRE AT LEAST ONE REVIEW AND APPROVAL OF ANY RESEARCH CONDUCTED ON GUAM WITH REGARD TO HUMAN SUBJECTS BY A GUAM-BASED INSTITUTIONAL REVIEW BOARD

Finally, **Delete** section 24102. ***Board; Terms; Appointment; Continuance; Removal.***, Page 4 lines 19 through 40.

UOG TESTIMONY TO REVISE BILL No. 347

Greetings to Senator Kasperbauer and other senators!

I am also here today to testify that Bill No. 347 must be revised before it is forwarded to the full body of the 24th Guam Legislature. There are four reasons for the revisions that I wish to address: 1) duplication of the existing review process; 2) the role of the University of Guam in research; 3) delays in conducting research; and 4) the composition of the committee.

Let me begin by discussing duplication of the existing review process and suggesting a change in the legislation. The University of Guam's Committee on Human Subjects in Research (CHSR) has existed since 1982 and its members actively serve the citizens of Guam by providing protection. Members review 20 to 30 research proposals per year; these are submitted by faculty conducting research on human subjects, by graduate students conducting thesis research in the Department of Education and other agencies, and by undergraduate students conducting research in Guam's classrooms. Those participating in the research are adequately protected in accordance with the U.S. federal and local regulations related to human subjects in research.

The change we are suggesting is that the "creation of the Guam Research Review Board" be replaced with " the designation of the University of Guam's Committee on Human Subjects in Research as

the Institutional Review Board (IRB) for researchers and collaborators at the University and for researchers who are not under other IRBs." Wherever the bill states "Guam Research Review Board" it should be replaced with "UOG's Committee on Human Subjects in Research."

Second, I wish to state that the role of the University of Guam in research is that of the state institution and, as such, it is appropriate that the IRB be housed in the Office of Graduate School and Research. However, GS&R has as its primary duty service to graduate students, and it is already overburdened with increases in the number of graduate students enrolling in courses, increases in the number of graduate programs since 1993, and increases in the number of qualified graduate faculty who seek answers to questions. In order to meet the stipulations of the legislation, GS&R needs funding and the creation of a new clerical staff position. Please include appropriate funding as this legislation goes forward.

clerical staff and resources

UOG has a fine record of grantsmanship and compliance with federal standards because it strives to meet rules and regulations through the policies set by Research Council and enforced by GS&R.

The third issues I will briefly address is the concern that an added review process would cause delays that could hinder the excellent research that is presently being conducted by undergraduate students in various programs. Undergraduate students only have one semester or fifteen weeks in which to complete their research projects. It is our desire to encourage undergraduate students to conduct research under the mentorship of their professors. Review processes take time to complete , but unusual delays could damage a student's enthusiasm for the research project. The UOG's Committee on Human Subjects in

Research is currently expediting the review process for undergraduate students who have limited weeks to complete research.

Finally, I will state my concerns about the composition of the committee. Section 3 on page 4 states the proposed composition of the Guam Research Review Board. This entire section of Bill No. 347 should be deleted and replaced with the composition of the CHRS which is:

3 or 4 professional research proficient experts from UOG

at least 1 Guam community representative

at least 1 local religious leader

at least 1 licensed practicing local medical doctor

This composition allows the IRB to remain relatively free from political interference. The UOG President is kept informed of changes in the membership and may appoint qualified members to the CHSR when there are vacancies.

Let me assure you, senators, that I am willing to revise Bill No. 347 by working with you and your staff. We all need to work towards the protection of the citizens of Guam who agree to participate in research projects.