SECTION - THERAPY SERVICES
ADMINISTRATIVE DIRECTIVE NO. 414
(Replaces AD 414 dated 1/19/06)

Effective Date: December 7, 2006

SUBJECT: RESEARCH

I. PURPOSE

To recognize that the understanding, prevention, and amelioration of mental health problems depend upon knowledge gained through research.

II. AUTHORITY

A. The California Department of Mental Health Special Order No 228.

B. The California Health and Human Services Agency's Assurance of Compliance with the Department of Health and Human Services Regulations for the Protection of Human Subjects.

C. United States Department of Health and Human Services Regulations for the Protection of Human Research Subjects (Title 45 of the Code of Federal Regulations, Part 46, as amended).

D. Regulations of the Food and Drug Administration (Title 2l of the Code of Federal Regulations) when the uses of drugs are involved in research.

III. POLICY

A. It is the policy of this hospital to encourage hospital personnel and investigators who are not staff members, who are equipped by interest and training, to conduct applied and basic research. To this end, research resources and assistance will be provided within the capacity of the hospital.

B. Consideration will be given to assigning a hospital staff member to assist and/or supervise research investigators who are not members of the hospital staff.

C. Research is defined as a systematic investigation designed to develop new knowledge of a basic or applied nature. It can include work prepared as part of the requirements of post-graduate training such as dissertations and theses.

D. Program evaluation, in contrast to research, aims to monitor the effectiveness with which existing knowledge is applied. Program evaluation does not require the same review and approval as research investigations.

E. Several elements are considered in whether a study is or is not research. A "yes" answer to any of the following questions constitutes a research study:

1. Is the study designed to be experimental or quasi-experimental? (i.e., is there an intent to control or isolate specific variables and then to measure the effect of applying or removing them?)

2. Does the study introduce additional patient evaluation or monitoring procedures that are not a part of standard clinical practice at the hospital? (i.e., is the Individual asked to do something not inherent or customary in the delivery of the care he is receiving?)

3. Does the study require additional actions in monitoring or evaluating Individuals that are not essential to delivering safe and effective treatment to the Individual? (i.e., are staff being asked or agreeing to complete tasks which are not inherent or customary in the delivery of patient care at the hospital?)

4. Does the study require the gathering of identifiable patient-record information that is not a function of delivering treatment to the Individual or essential to administrative reviews of hospital performance?

5. Is the intent of the study to monitor the effectiveness of the treatment provided to our Individuals or to pursue some individual professional agenda? This entails an evaluation of the investigator's reasons for pursuing the study. If the intent is primarily for professional publication or presentation, then it is not program evaluation and by default becomes research.

6. Is the area of investigation outside of the employee's routine responsibilities? (e.g., whereas analyzing data on Individuals who are directly under a professional's care may fall under program evaluation, analyzing data on Individuals that one does not routinely assess or treat, by default, becomes research.)

IV. METHOD

A. Research and Human Subjects Committee

1. Recognizing that the understanding, prevention, and amelioration of mental health problems depend upon knowledge gained through research. The Research and Human Subjects Committee shall have a multidisciplinary and broad based composition, including, when possible and appropriate, at least one community member. Committee members shall be qualified to evaluate research proposals based on their training and experience. Such qualifications may include formal coursework in experimental methods or statistics, knowledge of appropriate ethics and standards of research, and previous research experience.

2. Where appropriate, the Research and Human Subjects Committee shall seek expert consultation from non-members. This may include legal advice when necessary.

3. The Research and Human Subjects Committee shall advise the Executive Director in administrative matters related to research and the use of human subjects at the hospital.

4. The Research and Human Subjects Committee shall review submitted research protocols at the hospital as an agent of the California Health and Human Services Agency's Committee for the Protection of Human Subjects.

5. The Research and Human Subjects Committee shall have the responsibility of monitoring all on-going research.

B. Hospital Coordinator of Research

1. The Chairperson of the Research and Human Subjects Committee is the established Hospital Coordinator of Research.

2. The Hospital Coordinator of Research, in conjunction with the Research and Human Subjects Committee, shall implement hospital policies governing re search.

3. The Hospital Coordinator of Research shall implement and communicate decisions of the Research and Human Subjects Committee.

4. The Hospital Coordinator of Research shall serve as liaison between researchers and the hospital.

   a. The Hospital Coordinator of Research shall acquaint potential researchers with the requirements of hospital policies and procedures.

   b. As appropriate, the Hospital Coordinator of Research shall advise researchers on preparing research protocols.

   c. The Hospital Coordinator of Research facilitates the activities of researchers by serving as the liaison to the treatment programs and service units of the hospital.

5. The Hospital Coordinator of Research prepares reports to the Executive Director, Medical Director, the Department, and other agencies as required.

6. The Hospital Coordinator of Research disseminates research results and findings within the hospital.

7. The Hospital Coordinator of Research administers the Oath of Confidentiality wherever applicable.

8. The Hospital Coordinator of Research shall maintain records on all research activities, including the following:

   a. Departmental, Agency, and Federal regulations.

   b. Correspondence regarding research.

   c. Transactions of reviewing bodies.

   d. Files on each research project that includes a research protocol, dispositions, progress and final reports, and vitae of the investigators.

   e. List of all Research and Human Subjects Committee members and their qualifications.

V. REVIEW AND APPROVAL PROCEDURE

A. Program Evaluation Studies/Presentations and Publications:

Program evaluation studies do not require Research Committee review and approval. Generally, these activities are approved at the program or department level and are conducted at the behest of the program or departmental manager (e.g., Clinical Administrator, Medical Director, Program Director, EDS Director). When the study is being initiated and completed without the direct involvement of the area manager, a brief descriptive memorandum describing the intended study must be submitted to the Coordinator of Research for review and approval prior to affecting the study.

In disseminating findings of a program-evaluation study, the Executive Director's approval is required for the submission of results of such studies for publication or for their usage in formal presentations at any outside conference, workshop, or similar professional setting. This process is coordinated by the Public Relations Officer. Also, see AD No. 154 (Public Relations) for approval of other documents intended for publication, including review articles and theoretical papers or books, that involve data or any other information derived from the context of employment at the hospital. Prior to such publication or presentation, it is expected that the study's results will be made available to our staff, through appropriate in-house presentations and informational memoranda.

B. Research Studies:

1. Approval by the Research and Human Subjects Committee and the Executive Director is required prior to conducting any research project which involves the use of human subjects or identifiable private information (e.g., medical records, personnel records, etc.). Research studies that do not include the use of human subjects or identifiable private information need to be reviewed by the Coordinator of Research, but may not need to be reviewed by the Research and Human Subjects Committee. Approval of the Executive Director is still necessary.

2. Principal Investigators will initiate the review process by submitting a protocol in a format prescribed by the Research and Human Subjects Committee to the Hospital Coordinator of Research. A proposed budget for the study and the vitae of the investigators will be attached to each protocol.

3. Protocols that satisfactorily meet the formal requirements, as determined by the Hospital Coordinator of Research, will be assigned a research number and forwarded to the Research and Human Subjects Committee. The committee will review the protocol within 30 days of submission.

4. In reviewing a project proposal, the committee shall evaluate the protocol's conformance with the State and Federal guidelines for the protection of human subjects, and consider specifically:

    a. The qualifications of the researcher. Supervision by a scientifically and professional qualified practitioner shall be established when appropriate. In studies where body integrity may be violated, or when otherwise appropriate, medical liaison or supervision shall be included.

    b. The adequacy of the research design and the scientific merits of the research proposal.

    c. The implementation of ethical standards in the design. To the extent appropriate, research protocols shall be reviewed according to the standards of the profession to which the investigator(s) belong.

    d. The nature of the risks involved, if any. Experimentation should be planned in such a way as to avoid pain, suffering, or inconvenience to the research participant and his/her family or conservator. Procedures for detecting untoward consequences shall be stated in the research protocol.

e. The adequacy of procedures to cope with and remedy untoward consequences. Procedures for dealing with untoward consequences must be stated in the protocol and treatment implemented. Upon completion of the research procedures, the principal investigator is responsible to alleviate, to the extent possible, any confusion, misinformation, stress, physical discomfort or any other harmful consequences that may have arisen from participation in the study.

f. The specific and general benefits to be derived from the project.

g. The risk/benefit ratio - potential benefits must outweigh the risks involved.

h. The adequacy of the informed consent procedure.

i. The adequacy of the informed consent form.

j. Procedures to account for the use of protected health information.

k. The feasibility of conducting a particular research project, given the hospital's mission and resources.

l. Any other aspects deemed to be important by the committee.

5. Any committee member directly involved with a research project under consideration shall abstain from voting on issues related to that project. No research project with which a majority of the members of the Research and Human Subjects Committee is directly associated shall be considered.

6. In reviewing research proposals, the committee may invite appropriately qualified individuals from within or outside the hospital, as consultant members when considering proposals requiring special competence. Usually, consultant members will be selected from the discipline(s) involved in the project, in consultation with the professional staff group(s) concerned.

7. The Research and Human Subjects Committee may take any of the following actions regarding a research protocol:

a. Determine that review and approval of the protocol is not necessary as it does not constitute research or it does not involve the use of human subjects or private identifiable information.

b. Recommend approval of the protocol to the Executive Director.

c. Recommend approval of the protocol to the Executive Director contingent upon the completion of specific revisions.

d. Deny approval of the protocol.

8. Disapproval of a protocol by the Research and Human Subjects Committee may be appealed by the principal investigator(s) to the Hospital Executive Director who may, in turn, request review and opinion from the California Health and Human Services Agency's Committee for the Protection of Human Subjects. If such a project is approved, implementation is subject to the authority of the Hospital Executive Director in conjunction with the Medical Director.

9. Protocols recommended for approval by the Research and Human Subjects Committee will be forwarded to the Hospital Executive Director for approval. The Executive Director will act on the protocol within seven days of approval by the Research and Human Subjects Committee.

10. Two copies of protocols approved by the Executive Director will be forwarded for review and approval to the Deputy Director, Long Term Care Services of the Department of Mental Health. The Deputy Director should provide a decision within 7 days.

11. Protocols approved by the Deputy Director will be forwarded to the California Health and Human Services Agency Committee for the Protection of Human Subjects. That committee generally reviews the protocol within 60 to 90 days.

12. Researchers seeking outside funding may be required to obtain certain additional approvals. It is the investigator's responsibility to fulfill all requirements for grant applications.

VI. INFORMED CONSENT

A. Participation in research by Individuals, relatives, and employees of the hospital must be obtained on a voluntary basis in strict conformity with the principles governing informed consent. Specific guidelines for obtaining informed consent are detailed in Appendix II of the "Instructions for Researchers" promulgated by the California Health and Human Services Agency Committee for the Protection of Human Subjects.

B. All participants in a research project shall be given the following information prior to seeking their consent/assent:

1. A description of the benefits to be expected from the research;

2. A description of the potential discomforts and risks that may accompany their participation;

3. A description of alternative services that might prove equally advantageous to them;

4. A full explanation of the procedures to be followed, especially those that are experimental in nature.

Any refusals to participate in the study will not compromise access to services that is regularly provided to Individuals at this hospital.

C. Investigators may defer full disclosure of the purpose, nature, expected outcome, and implications of the research to potential subjects prior to participation, only if it can be fully justified to the Research and Human Subjects Committee that such declaration is inadvisable and to defer it is not detrimental to the subjects. Under such conditions, provisions must be made for full disclosure to participants at the completion of the project.

D. All informed consent forms must include the subject's name, signature, the date consent was obtained, the local research number and title of the project, and the signature of a witness or the Individual who supplied the subject with information about the study. Consent forms will also address the participant's right to privacy, confidentiality, and safety.

E. It is the responsibility of the Principal Investigator(s) to determine if potential participants in research are legally and functionally competent to provide informed consent. All prospective participants who are incompetent to provide informed consent for research shall participate only if informed consent has been given by a person legally empowered to do so for the participant.

F. Principal Investigator(s) will place a signed informed consent form in the medical record of all Individuals participating in a research study.

G. Requirements for informed consent may be waived upon the request of the Principal Investigator(s) and the approval of the Research and Human Subjects Committee when the risk to the subject is minimal, or if the procedures for obtaining the informed consent would invalidate objectives of immediate importance and any reasonable alternative means of obtaining these objectives would be less advantageous to the subjects.

VII. CONFIDENTIALITY

A. Investigators must be guided by the regulations of confidentiality and must comply with additional confidentiality commitments when they are made to research participants.

B. Any reports of the results of a research study will safeguard the confidentiality of the participants. No disclosure of individually identifiable health information will be made without written patient authorization. The hospital may assign a code or other means of record identification, provided that the code which can be used to re-identify the information is treated as protected health information.

C. Investigators and their assistants who are not employed at the hospital must sign an Oath of Confidentiality administered by the hospital's Coordinator of Research.

VIII. MODIFICATIONS AND RENEWALS

A. All research projects must be conducted in conformance with the protocol and procedures that were approved. Any changes in research design or procedure must be submitted to the Research and Human Subjects Committee for review. Approval by this committee, the Executive Director, the Division of State Hospitals and the California Health and Human Services Agency Committee for the Protection of Human Subjects is required prior to implementing any changes.

B. Projects that extend beyond a one-year period must be renewed at least annually, pursuant to the requirements of the California Health and Human Services Agency Committee for the Protection of Human Subjects. Two months prior to the yearly anniversary date of the project's approval, the Principal Investigator(s) shall initiate a renewal request directly to the agency's committee, with a copy of that request sent to the Coordinator of Research.

C. Any project involving more than minimal risk to human subjects shall include a monitoring procedure determined by the Research and Human Subjects Committee. This procedure shall ensure that the project functions within the guidelines for the protection of human subjects and the constraints specified in the approval of the project.

IX. RESEARCH RECORDS AND REPORTING OF RESULTS

A. Research data and records on research conducted at this hospital are the property of the hospital unless other arrangements are made with the approval of the Executive Director. Investigator(s) in possession of research data and records will furnish copies, when necessary, to qualified personnel in the hospital within the context of safeguarding confidentiality commitments made to the research participants.

B. Research, by its nature of being based on the principle of verification, is a public enterprise. Consequently, research results need to be disseminated.

1. Investigators will prepare progress reports to the Coordinator of Research as required by the Executive Director.

2. Prior to submission for publication:

   a. Research reports of studies that have been approved by the California Health and Human Services Agency Committee for the Protection of Human Subjects Committee shall either be approved by the Executive Director or shall clearly state that "the article does not necessarily represent the view of Coalinga State Hospital or the California Department of Mental Health".

   b. All other research and program evaluation reports shall be approved by the Executive Director prior to publication, and the Executive Director may require that the report include the statement: "The article does not necessarily represent the view of Coalinga State Hospital or the California Department of Mental Health".

3. Investigators will furnish final reports and reprints of published studies to the Executive Director. The materials will be maintained in the Hospital's Professional Library.

W. T. VOSS
Executive Director

Cross Reference(s):
A.D. No. 154 Public Relations
A.D. No. 438 Clinical Outcome Evaluation System