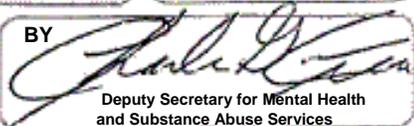


	MENTAL HEALTH AND SUBSTANCE ABUSE SERVICES BULLETIN		
	<small>COMMONWEALTH OF PENNSYLVANIA</small>		<small>DEPARTMENT OF PUBLIC WELFARE</small>
DATE OF ISSUE July 28, 1999	EFFECTIVE DATE Immediately	NUMBER OMHSAS-99-06	
SUBJECT Mental Health Research Involving Human Subjects		BY  <small>Deputy Secretary for Mental Health and Substance Abuse Services</small>	

SCOPE:

The attached guidelines apply to all research involving human subjects that is conducted at a state mental hospital or the state restoration center.

PURPOSE:

To provide each state mental hospital and the restoration center with guidelines to follow when conducting research involving human subjects

In order to receive reimbursement at these levels, counties must revise their county compensation plan, Personnel Action Plan, or Modified Classification Review Plan appropriately.

BACKGROUND:

The Department of Public Welfare/Office of Mental Health and Substance Abuse Services (OMHSAS) has responsibility for all research involving humans subjects. These regulations and guidelines began in 1964, with stipulations in the DPW Manual, Section 6950. In March 1979, the Office of Mental Health (OMH) issued guidelines, and again in Bulletin SMH 90-02, July 10, 1990. Current guidelines in this revised Bulletin are based on existing Commonwealth Law (i.e., Mental Health Procedures Act of 1976), the State Mental Health Manual (55 Pa.Code 5100.54, section d), and current federal regulations promulgated by the Food and Drug Administration (21 C.F.R., § 50.20, 50.21, July 23, 1997) and the Department of Health and Human Services (45 C.F.R., §§ 46.1 16-46.21 1, June 18, 1991).

The Department requires strict ongoing protection for those human research subjects having been identified as mentally ill. At the same time, the Department encourages research in mental health, with the intent of providing the most sophisticated and current monitoring and treatment of patients possible. Ongoing collaboration with the Pennsylvania training institutions, that has existed for many years, continues to be supported, as well as research collaboration among our state mental hospitals. Where ever possible and appropriate, research begun within the state hospital setting should be continued into community programs. Community program directors and state hospital researchers should work closely to this end.

The attached guidelines are updated to continue to provide the legal and human rights protection for persons with mental disabilities who are being treated in state operated mental health facilities

Obsolete Bulletin: SMH-90-02

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

Medical Director
717-772-2351

**COMMONWEALTH GUIDELINES
FOR HUMAN RESEARCH SUBJECTS
AT PENNSYLVANIA STATE MENTAL HOSPITALS
AND RESTORATION CENTER**

**Commonwealth Guidelines for the
Protection of Human Research Subjects**

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APPLICABILITY

- A. Except as provided in paragraph B. of this section, these guidelines apply to all research involving human subjects at state mental hospitals or the state restoration center.

- B. Research activities, in which the only involvement of human subjects is in one or more of the categories listed below, are exempt from these guidelines:
 - 1. Research involving only survey or interview procedures, except where the research can be identified directly to the subject or through identifiers linked to the subject(s).

 - 2. Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available.

 - 3. Research involving information recorded by an investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subject(s).

 - 4. Research involving the use of assessment tools (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified directly, or through identifiers linked to the subject(s).

- C. Investigators seeking exempt status for research proposals must submit a copy of their proposals to the Chair of the facility Research Review Committee and/or the Director of Research at the facility where the research is being conducted, and to the Deputy Secretary for Mental Health and Substance Abuse Services (OMHSAS) or his/her designee, for approval.

DEFINITIONS

Amendment - a change in the established research procedure or protocol, previously approved by the Office of Mental Health and Substance Abuse Services and by the Department. Research amendments require the local research review committee, the involved training facility and/or the federally-approved institutional review board, and the OMHSAS Medical Director's Office approval in writing. Substantial change may require resubmission of a research protocol, as determined by the Office of the Medical Director.

Federally-Approved Institutional Review Board (IRB) - an institutional review board, approved by the U.S. Department of Health and Human Services, providing contracted independent outside review of a proposed research project in circumstances where the research is not done in collaboration with a Pennsylvania medical training institution, and thereby the proposed research does not have the opportunity for outside review.

Department - the Pennsylvania Department of Public Welfare.

Human Subject - an individual from whom a researcher obtains information through records, testing or direct contact.

Individually Identifiable - a variety of circumstances in which the research subject may potentially be identified.

Intervention - medical or environmental manipulative procedures necessary for research data gathering, e.g., venipuncture, the need for transportation of subjects, or the need for geographic relocation of subjects for the purposes of the study.

Interaction - communication or interpersonal contact between investigator and research subject.

Individuals Hospitalized with Mental Illness Diagnoses - individuals who have been admitted voluntarily or involuntarily to facilities for the treatment of mental disorders. Such admission includes, but is not limited to, public or private mental hospitals, psychiatric units of general hospitals, and individuals residing in community residential facilities and nursing homes.

Legally Authorized Representative - any individual or entity authorized under appropriate state law to consent on behalf of the prospective research subject.

Permission - a written agreement of a guardian(s) to allow a ward's participation in research.

Minimal Risk - a circumstance in which no harm greater than ordinarily encountered in daily life is anticipated, or when discomfort anticipated is no greater than that found in routine physical or psychological examinations.

Non-Hospitalized Individuals - control subjects not housed in a 24-hour facility for the treatment of mental illness.

Office – The Office of Mental Health and Substance Abuse Services (OMHSAS)

Pathological Specimen – any body tissue or fluid removed for diagnostic or therapeutic purposes.

Pennsylvania Training Institution – one of the currently accredited Pennsylvania medical schools with whom OMHSAS has established an agreement to provide research collaboration, using state facility subjects.

Research – a systematic investigation designed to develop and/or contribute to greater knowledge and understanding in the field being studied.

Sponsor – a facility or entity in which the patient population resides or participates in treatment.

INTRODUCTION

The Office of Mental Health and Substance Abuse Services (OMHSAS) affirms that research activities are essential to investigate new and potentially better methods for establishing diagnoses, care, treatment, and prevention of mental illness. OMHSAS wishes to encourage quality research in mental health, recognizing that research policies must protect the rights and welfare of all hospitalized, as well as non-hospitalized, patients. This document addresses issues of concern regarding research involving human subjects in state mental hospitals and the state restoration center.

The Department of Public Welfare (DPW) has previously issued regulations [Mental health manual, Bill of Rights for Patients, Article VI, section 2(d), 55 Pa. Code, 5100.54] affirming "No patients shall be the subject of any research, unless conducted in strict compliance with Federal Regulations on the Protection of Human Subjects." Patients being considered for research studies shall have facility research committee approval, shall receive and understand the nature of the research, the expected benefits, and potential risks. Copies of appropriate federal regulations shall be made available to all patients or their advocates, involved in, or considering becoming involved in, research.

All research involving human subjects occurring at a state mental hospital, or at the state restoration center, shall be subject to these guidelines.

PROCESS REVIEW AND GUIDING PRINCIPLES

Strict review of proposed research projects prior to implementation is required to protect the legal and human rights of the subjects involved. The evaluation requires that each facility engaged in research establish a research review committee(s). The method of establishing the committee(s) is determined by each facility, with the joint concurrence of the medical staff and the hospital administrator. The facility committee should comprise members of diversified backgrounds, trained and experienced in research procedures, conversant with patient population and limitations of a facility, and knowledgeable about protecting the civil rights of subjects. The committee is expected to provide continuous review of the research study, when appropriate. The facility committee should have one (1) member not associated with the institution.

Concurrent with, or subsequent to, facility research committee review, the research protocol must be reviewed and receive approval from a Pennsylvania training institution research review board, or when research is not performed in collaboration with such a state training program, approval be sought from an independent federally-approved institutional review board.

In summary, the facility superintendent/administrator is responsible for the operation and integrity of the research review committee and promoting a positive environment suitable to relevant research. State mental health facilities are required to include language supporting a positive facility approach to research in its mission statement.

FACILITY RESEARCH REVIEW COMMITTEE(S) MEMBERSHIP REQUIREMENTS

Research review committee(s) shall comprise, as a minimum, the following members, and shall establish its composition under the following guidelines:

1. Comprise at least a minimum of five (5) members with diversified backgrounds allowing adequate coverage of the broad range of anticipated mental health research being considered.
2. Committee members will be continually cognizant of protecting the right and welfare of prospective research subjects.
3. When possible, facility research members should include the following representation: psychiatric physicians, non-psychiatric medical specialists, research scientists, psychologists, nurses or nurse practitioners, physician's assistants, attorneys, social workers and chaplains.
4. Committee members shall understand the institutional mission and the regulations under which it operates, applicable state and federal laws/regulations regarding human research, standards of best practices, and standards of professional conduct.
5. No committee shall comprise representation from only one profession.
6. Each committee shall have a minimum of one (1) member of a non-medical or non-scientific profession (e.g., law, clergy).
7. Each committee shall include one (1) consumer of mental health services and one (1) advocate or family member of a consumer.
8. Committee chairs will be elected by the committee or appointed by the facility superintendent/administrator and serve for a defined period.
9. Committee term appointment is recommended for 2 or 3 years, with one additional term possible, at the discretion of the members and the superintendent/administrator.
10. To allow continuity of functioning, member's terms shall overlap. Every attempt shall be made to maintain a full membership complement.
11. A committee quorum shall consist of a majority of members assigned to the committee.

FACILITY RESEARCH REVIEW COMMITTEE(S) FUNCTIONS

Facility research review committee(s) shall be responsible for each of the following:

1. Establish facility committee structure and procedures and forward appropriate current documents to the OMHSAS.
2. Evaluate facility research proposals individually for scientific and technical merit, in accordance with parameters of these guidelines and in accordance with current federal and state standards regarding the protection of human subjects used in research. Committee members sponsoring proposed research are to be excused from the review and voting process. All research investigators, at the request of the Committee, however, will be available for proposal review, but shall not vote for approval/disapproval of the research being considered.
3. Render decision for each proposal under consideration by majority committee membership vote and determine one (1) of the following options:
 - a. Approve proposal and forward proposal to Pennsylvania training institution(s) or contracted independent review board for concurrence;
 - b. Disapprove and specify reason(s) for rejection
 - c. Defer decision, pending clarification, or until further information can be provided to the Committee for their deliberation.
4. Monitor approved research projects for appropriateness and scientific merit, patient protection, risk, and adherence to facility and Department standards on a yearly basis.
5. Provide counsel and technical assistance to research investigators when necessary, including the protection of rights of human subjects.
6. Provide independent expert consultation, outside the facility if necessary, as required by researchers or as requested by Committee members. Consultants may not vote on Research Committee matters.
7. Accept responsibility for reporting to the facility superintendent/ administrator, and the Medical Director and Deputy Secretary of OMHSAS, serious non-compliance with the requirement(s) established by the Committee.

REQUIREMENTS FOR APPROVAL OF PROPOSED RESEARCH

Research proposal approval depends upon each of the following requirements being met:

1. Human subjects being considered for research will not be at excessive risk; if risk be present, the risk is reasonable in relation to the anticipated benefits and knowledge obtained. Risk to subjects shall always be minimized and the research design will utilize accepted diagnostic and treatment standards, wherever possible.
2. Informed consent will be obtained in concordance with federal and state mandates covered in 45 C.F.R. §§ 46.1 16-46.1 17, 21 C.F.R. § 50.20-50.27 and 40 P.S. § 1301-A(b), and appropriately documented. Coercion and undue influence will not be permitted.
3. Research methodology will be appropriate to the objectives of the study, suitable to the population proposed, and personnel and equipment used will be adequate to provide patient protection.
4. Research investigators and staff must possess adequate credentials and experience to complete the study in an expedited fashion and in a manner consistent with the intent of these guidelines.
5. Adequate provisions to protect the privacy of subjects and the confidentiality of data will be maintained.
6. Research will be conducted in the least disruptive fashion to ensure adequate continuity of care and present minimal disruption to facility operations.

OUTLINE FOR RESEARCH PROPOSAL REVIEW

ENTITY	REQUIREMENT
Applicant	1. Prepare and forward copies of the research proposal to the Superintendent/Administrator of the facility, the Director of Research, and/or the Chairperson of the Research Review Committee where the research is being conducted.
Chair, Research Review Committee	2. Confirm requirement #1 is fulfilled. As a minimum, assign two (2) committee members to conduct independent reviews of the proposal, or distribute the proposal to the entire committee for review. Assignments are to be made on the basis of experience and expertise on the subject under consideration. If committee member composition does not include the expertise required, seek and assure outside consultants to satisfy requirements.
Committee or Consultant Reviewers	3. Ensure that the findings of the assigned reviewers and/or the discussion of the committee as a whole are recorded in committee minutes or available in a written summary. The minutes or the written summary will be retained by the Chair, Research Review Committee.
Chair, Research Review Committee	4. Ensure thorough committee familiarity and understanding of the original proposed research. When concomitant approval has been sought by either a Pennsylvania training facility or an outside independent Institutional Review Board, make those findings available to the committee. Committee discussion should center on appropriateness, technical and scientific merit, adherence to facility guidelines, patient protection, and assurance of non- coerced informed consent.
Research Review Committee	5. Decisions are made by a majority vote of members. Approved research proposal should be forwarded to the Institutional Review Board of a PA Training Institution or a federally-approved independent Institutional Review Board. Disapproved research should be returned to the sponsoring investigator with reasons far denial. Deferral, and requests for further clarification or additional information, should be returned to the sponsoring applicant with instructions regarding the committee's requirements.

Institutional Review Board	6. Review proposed research for compliance with these guidelines and stipulated for the facility in which the research is being conducted. Forward written findings to the Chair, Research Review Committee.
Chair, Research Review Board	7. Where positive action is warranted, forward a packet comprised of the original research proposal and subsequent inclusions (if applicable), the written findings of the Research Review Committee and the Institutional Review Board, and all applicable documentation, to the Superintendent/ Administrator of the facility and to OMHSAS Medical Director, who acts in a review capacity for the Deputy Secretary, OMHSAS.
Medical Director, OMHSAS, or his/her designee	8. Evaluate the research proposal packet for its technical and scientific merit, its adherence to state and federal guidelines, its appropriateness to the Mission of OMHSAS, its protection of subjects, and its relevance to the mental health research requirements/needs of the Office. Forward affirmative decisions to the Deputy Secretary for approval.
Deputy Secretary, OMHSAS	9. Approves or disapproves the proposal based upon previous review and assessment.
Deputy Secretary, OMHSAS, or his/her Designee	10. Notifies the facility Superintendent/Administrator, the applicant sponsoring the research, and the Chair, Research Review Committee, of OMHSAS' decision.
Chair, Research Review Committee	11. When OMHSAS disapproval or deferral occurs, inform the research applicant in writing of suggestion(s) for correction, deficiencies requiring attention before approval, or the reason(s) for rejection.
Chair and Members, Research Review Committee	12. Assures that the principal investigator communicates the purpose, nature, expected outcome, and practical and theoretical implications of the research to the appropriate facility staff in a manner which is readily understood.
Chair and Members, Research Review Committee	13. Monitors serious Adverse Drug Reactions (ADRs), forwards compiled data and actions taken to the Office of the Medical Director, and shares information with collaborating research staff, facilities, and sponsoring programs.
Chair and Members, Research Review Committee	14. Provide at least yearly evaluations to confirm continued compliance of current research with provisions of these guidelines.

RESEARCH FORMS GUIDELINES

The Office of Mental Health and Substance Abuse Services (OMHSAS) requires no specific research forms to accomplish the intent of this Bulletin. Guidelines established by individual facility research committee(s), the research committees of the Pennsylvania training institutions, and requirements of collaborating organizations and contracted independent institutional review boards approved by the federal government, may well dictate the forms that are required for research proposal approval.

The following forms are provided as suggestions for facility use when other dictates do not necessitate the use of specific forms. Facilities should feel free to use these forms, modify the attached forms, or develop other forms as local requirements dictate.

I. Research Proposal Outline

This outline should provide basic informational elements and must include the following:

1. Project Title, Principal Investigator, and Submission Date;
2. Current IRB number (if assigned) and INDIIDE number;
3. Principal Investigator's title, address, phone and FAX numbers;
4. Research coordinator's name and phone number;
5. Names of co-investigators;
6. List of all investigation sites, primary and secondary, with number of subjects at each site, estimating gender and age range;
7. Duration of participation per subject and duration of research study;
8. Estimation of level of risk: minimal, moderate, or high;
9. Prior scientific review with names of committees and facilities, specifying dates of approval;
10. Sources of research funding;
11. Statement affirming the principal investigator and co-investigators have no conflict of interest in pending research, i.e.: (1) own, control, or have equity interest in the technology of the research, (2) financial interest in sources of external support, or (3) major role in listed commercial source of external support;
12. Statement affirming the cost of procedures performed will not be charged to the research subject or his/her insurance provider;

13. List of study drugs or devices;
14. Statement addressing any exposure to ionizing radiation. If exposure expected, affirming in writing HUSCIRDRC approval letter; and
15. List of the diseases being studied and the condition/problem(s) being evaluated.

II. Research Review Committee Evaluation

This evaluation form should address each of the following elements:

1. Research title;
2. Adequacy of methodology of present research design and probability of completion of the project as presented;
3. Suggested improvement(s) of the methodology, if applicable;
4. Adequacy of patient protection and suggestions for improvement, if applicable;
5. Statement of approval or deferral with mandatory suggestion(s) for approval; and
6. Signature of Committee Chair or Representative.

III. Statement of Informed Consent

Research covered by these guidelines will be provided with effective informed consent by the subject or the subject's legally authorized representative in a manner readily understandable. No informed consent, whether written or oral, may include any exculpatory language through which the subject or the subject's legally authorized representative is made to waive, or to appear to waive, the subject's legal rights, including any release of the facility or its agents from liability for negligence.

A. Elements of Informed Consent;

In order to meet the standard of this Bulletin, the following basic and additional elements of informed consent shall be provided:

Basic Elements of Informed Consent

In seeking informed consent, the following information shall be provided to each subject:

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, 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 and that notes the possibility that the Food and Drug Administration may inspect the records;
6. For research involving more than minimal risk, an explanation 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 about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject;
8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additional Elements of Informed Consent

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 to the subject (or to the embryo or fetus, if the subject is or may be pregnant) which are currently unforeseeable;
 2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
 3. Any additional costs 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 be related to the subject's willingness to continue participation, will be provided to the subject;
 6. The approximate number of subjects involved in the study.
- B. The informed consent requirements in this bulletin are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective.
- C. Nothing in these regulations 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 local law.

D. Exception to Informed Consent Criteria

The elements of informed consent set forth in this Bulletin need not be followed if the facility research committee agrees to the informed consent exception and the following occurs and is documented:

1. The research involved no more than minimal risk of harm to the subject;
2. The withholding or altering of the consent form will not adversely affect the rights and welfare of the subject; and
3. The research could not be reasonably carried out without the withholding or alteration of the consent form.

IV. Research Study Annual Report

A. The annual report should contain each of the following:

1. Required date of submission;
2. Protocol title;
3. Principal investigator, office address and phone number;
4. Renewal interval: annual or other;
5. Number of subjects entered during renewal interval;
6. Number of total subjects entered into the protocol;
7. Withdrawals during renewal interval and reasons: ADRs or unexpected events, with appropriate documentation;
8. Apparent changes in the benefit-to-ratio of study participants, with documentation;
9. Presence or planned changes of previously approved research protocol or informed consent document(s);
10. Statement affirming ongoing nature of research and/or estimate of termination of study; and
11. Signature of principal investigator and date.

V. Adverse Drug Reaction Form

A. The Adverse Drug Reaction (ADR) form should contain each of the following elements:

1. Protocol title with appropriate FDA-IND#;
2. Name, title and phone number of principle investigator;
3. Investigational drug under consideration;
4. Study size: number of patients planned for enrollment and number of patients enrolled to date;

5. ADR Information:

- (a) Nature of ADR;
- (b) Number of prior reports of % of subjects under study;
- (c) Classification: serious, unexpected, or increased frequency;
- (d) Assessment of causality: remote, possible, probable, or highly probable;
- (e) Location of ADR;
- (f) Affirmation or denial of event listed in current investigational drug material;
- (g) Statement of presence or absence of event on current consent form;
- (h) Suggested recommendations to protocol or consent form, if applicable; and
- (i) Signature of Chair/Committee Representative.

Reference Bibliography

1. Department of Health and Human Services (DHHS), 42 Code of Federal Regulations (C.F.R.) § 2.21 and Part 2A (Confidentiality of Alcohol and Drug Abuse Patient Records)
2. The Pennsylvania Code, Title 55 (Pa. Code of Public Welfare, Chapter 5100, Mental Health Procedures §§ 51 00.31-51 00.39 (Mental Health Manual)
3. 45 C.F.R. §§ 46.1 16-46.21 1 (HHS Protection of Human Research Subjects)
4. 21 C.F.R. §§ 50.20, 50.21 (Informed Consent of Human Subjects)
5. Fay Rozovsky, Consent to Treatment, Chapter 8 (2d ed. 1990 & supp. 1998) (Recommendations for practitioners)
6. The Joint Commission on Accreditation of Hospital Organizations (JCAHO) standards: The Comprehensive Accreditation Manual for Behavioral Health Care, The Comprehensive Accreditation Manual for Long Term Care, and The Comprehensive Accreditation Manual for Hospitals, January 1998
7. 49 PA.Code S41.61 (Section of State Board of Psychology's Code of Ethics)
8. 40 P.S. § 1301-A (Section of Health Care Services Malpractice Act)
9. Dorothy Derrickson, Note: Informed Consent to Human Subject Research: Improving the Process of Obtaining Informed Consent from the Mentally Ill, 25 Fordham Urb. L.J. 143 (Fall 1997) (Suggestions for modifying currently legally acceptable procedures and not legally binding)
10. Morgan v. MacPhail, 704 A.2d 617 (Pa.1997) (PA Supreme Court Case)

Research Proposal

Project Title: Submission Date:

Principal Investigator: Title:

Address:

Phone Number:

IRB Number: IND/IDE Number:

Research Coordinator:

Address:

Co-investigators Names:

List of Investigation Site(s), estimated number of subjects at each site by gender and age range:

Estimated duration of participation per subject per site:

Estimation of risk level:

Prior review dates or research and facilities involved:

Funding resource(s):

Affirmation of no conflict of interest:

Affirmation no fees passed on to subjects or their insurance:

List of study drugs and devices:

Ionizing radiation statement:

List of disease(s) to be studied and condition/problem(s) being evaluated.

Research Review Committee Evaluation

Title:

Assessment of adequacy of methodology of design and affirmation of probability of completion:

Suggested methodological improvement (if applicable):

Statement affirming adequacy of patient protection and suggestion(s) for improvement, if applicable:

State of approval or deferral, with mandatory suggestions(s) for approval:

Signature of Committee Chair or Representative:

Informed Consent

Affirmation of understandable overview provided, including each of the following:

Nature of research;

Purpose, description, and duration of research;

Affirmation of time allowance for subject questions and clear identification of contact person(s);

Description of research benefits, risks, alternatives available, and compensation statement;

Confidentiality statement;

Affirmation of voluntary participation and withdrawal acceptance at any time;

Signature and date of subject and research investigator(s):

Informed Consent

A. Protocol Information

1. Protocol Title:
2. Principal Investigator:
3. Telephone:
4. Investigational Drug:
5. Study Size:

<u>Study Site</u>	_____	<u>Entire Study of Multi-Center</u>	_____
No. of Patients to be Enrolled:	_____		_____
No. of Patients Enrolled to Date:	_____		_____

B. Adverse Drug Reaction Information

1. Nature of Adverse Event
2. Incidence (%) of Number of Prior Reports:
3. Classification (Check all that apply)
 Serious Unexpected Increased Frequency
4. Causality
 Remote Possible Probable Highly Probable
5. ADR Location
6. Is event listed in the current investigational drug brochure?
 Yes No
7. Is event listed in the current consent form?
 Yes No

C. Recommendations

1. Are any changes in the protocol necessary?
2. Are any changes in the consent form necessary?
3. Signature _____ 4. Date _____

Research Study Annual Report

Required Date of Submission:

Protocol Title:

Principal Investigator:

Office Address:

Telephone Number:

Renewal Interval: **Annual** _____ **Other** _____

1. A total of _____ subjects have been entered into this research protocol at _____ during this renewal interval.

2. A total of _____ subjects have been entered into this research protocol at _____ since its initial approval.

3. During this renewal interval:
 - a. Have any subjects been withdrawn from the study?
NO _____ *YES _____
(*If yes, indicate the reason for withdrawal.)

 - b. Have there been any serious adverse events associated with the conduct of this protocol at this site, or if applicable, at other sites?
NO _____ *YES _____
(*If yes, please attach a summary of these events or other relevant materials.)

 - c. Have there been any unexpected (i.e., to include greater than expected severity or frequency) adverse events associated with the conduct of this research protocol at this site, or if applicable, at other sites?
NO _____ *YES _____
(*If yes, please attach a summary of these events or other relevant materials.)

 - d. Has there been any change in the benefit-to-risk ratio of study participation as defined in the currently approved research protocol and consent form?
NO _____ *YES _____
(*If yes, describe this change and how it will be conveyed to both current and future research subjects.)

