

Program Instruction

EOEA-PI-03-17

TO: Aging Service Access Points
 Area Agencies on Aging
 Councils on Aging
 Elder Law Projects

FROM: Jennifer Davis Carey

DATE: June 3, 2003

SUBJ: Elder Rights Review Committee

We would like to remind you again about the Elder Rights Review Committee (ERRC). As you may know, since 1977, the ERRC has had jurisdiction over proposals by any researcher seeking to do research, surveys, or market studies which seek access to clients of any Elder Affairs grantee, subgrantee, contractor or subcontractor. The ERRC receives the research proposal, meets with the researcher to discuss the proposal, in particular the informed consent form(s). It then votes to recommend approval, qualified approval or disapproval by the Secretary, and/or request additional information. The ERRC includes: Elder Affairs legal counsel, at least one other staff member from Elder Affairs, one physician with a background in geriatrics and social service issues, one social scientist who may be an employee of the Elder Affairs and three elders who are not employees of Elder Affairs.

The goals of the ERRC are to ensure that: elders receive adequate information regarding any research and experimentation involving them; elders are not exposed to more than minimum physical or psychological risk after careful review of the impact of any medical procedures to be performed or medication to be used during the research; the research provides some reasonable expectation of direct or indirect improvement in service or of the well-being to elders; elders understand and consent to any research; the research does not put undue pressure upon individuals to participate in the project through either financial or psychological means; and the privacy and confidentiality of participant-related information is protected.

If there are any questions regarding the Elder Rights Review Committee, contact Tom Chung, Ph.D at (617)222-7456 or Joel Semuels, General Counsel at (617)222-7461.

PROTECTION OF CLIENTS WHO ARE PARTICIPATING IN RESEARCH PROJECTS (ELDER RIGHTS REVIEW COMMITTEE)

6/3/2003

1. Scope and Purpose

(1) This Program Instruction sets forth requirements for the submission to the Executive Office of Elder Affairs and for Executive Office of Elder Affairs' evaluation of proposals for research, experimentation, surveys, market research or similar research or experimentation which would affect any clients of the Executive Office of Elder Affairs when any proposal seeks access to clients through the Executive Office of Elder Affairs or any of its grantees, subgrantees, contractors or subcontractors. The Secretary shall forward all appropriate proposals to the Committee. **Please note: It is not necessary to submit a research proposal or survey to the Elder Rights Review Committee (ERRC) if the subject of the research proposal or survey involves an assessment of programs or processes of Elder Affairs, any Aging Services Access Point(s), Area Agency(ies) on Aging or Council(s) on Aging which is initiated by such agency or entity, and in which such agency is participating with a research entity. In these cases, the agency or entity is responsible for assuring the informed consent of participants and safeguarding their personal data under existing privacy laws.**

2. Definitions

Client of the Executive Office of Elder Affairs means any person receiving services administered by agents, grantees, subgrantees, contractors or subcontractors of the Executive Office of Elder Affairs.

Committee means the Elder Rights Review Committee established by the Secretary pursuant to this Program Instruction.

Data means any information concerning an individual which because of name, identifying number, mark or description can be readily associated with a particular individual.

Elder means any individual aged 60 or above.

Grantee, Subgrantee, Contractor, or Subcontractor means any agency or organization in receipt of state and federal funds, either directly or indirectly from the Executive Office of Elder Affairs, including those funded under the Older Americans Act, as amended.

Informed Consent means written consent required by and conforming to section 4(2)(i) below given by a client who is physically and mentally capable of giving consent.

Project means any proposal which has been approved by the Secretary upon the recommendation of the Elder Rights Review Committee.

Proposal means any written statement of intent, conforming to section 4(2) which seeks to gain access to clients of the Executive Office of Elder Affairs or data pertaining to clients for the purpose of conducting research, experimentation, surveys, market testing or similar research or experimentation.

Researcher/Investigator means any person, agency, organization, corporation or institution wishing to gain access to clients of the Executive Office of Elder Affairs for the purpose of conducting research, experimentation, surveys, market testing or similar research or experimentation.

Secretary means the Secretary of Elder Affairs.

3. Elder Rights Review Committee

(1) Composition.

- (a) The Secretary shall appoint the Elder Rights Review Committee. The Committee shall be composed of no fewer than five members. The Secretary shall designate the Executive Office of Elder Affairs legal counsel as chairperson. The Committee's membership shall include:
1. Executive Office of Elder Affairs legal counsel;
 2. At least one other staff member for the Executive Office of Elder Affairs;
 3. One physician with a background in geriatrics and social service problems.
 4. One social scientist who may be an employee of the Executive Office of Elder Affairs;
 5. Three elders who are not employees of the Executive Office of Elder Affairs.
- (b) Whenever the Committee determines that its members do not possess the expertise required for the review of a proposal, it may consult with a person or persons who possess the requisite expertise and experience necessary for the review of a particular proposal at no additional cost to the Commonwealth. Such person may be an employee of the Executive Office of Elder Affairs.
- (c) The Secretary may appoint additional members to the Committee as (s)he deems necessary from time to time.

- (d) No Committee member shall participate in the evaluation of a proposal in which he has either a direct or indirect professional involvement or financial interest.
- (2) Function.
 - (a) The Committee shall review all proposals submitted pursuant to section 4.
 - (b) The Committee shall recommend to the Secretary approval, disapproval, or qualified approval of proposals.
 - (c) The Committee may request researchers/investigators that have submitted proposals, to submit any additional information that the Committee may reasonably require in order to make its determination.
- (3) Meetings. The Committee shall meet as necessary to review proposals and to act upon complaints filed pursuant to section 9.
- (4) Procedure at Meetings.
 - (a) A simple majority of the appointed members shall constitute a quorum.

4. Proposals

- (1) Researcher/Investigators shall submit a proposal in writing to the Secretary.
- (2) Such proposals shall include, at a minimum the following information:
 - (a) identification of the person or persons directly responsible for the conduct of the proposal, together with the credentials of the persons to carry out the project;
 - (b) objectives of the proposal;
 - (c) source of support of the project and guidelines of the funding source;
 - (d) type of data sought and the methods of gaining access to said data;
 - (e) methods and procedures to be employed in carrying out the proposal;
 - (f) detailed enumeration of all foreseeable risks and benefits;
 - (g) procedures to be followed in the event of the occurrence of adverse effects to any subjects;
 - (h) method of recruiting participants, including number and required characteristics;
 - (i) a copy of the Informed Consent Form to be used, which shall include, at a minimum:
 - 1. an explanation of the purpose of the proposal;
 - 2. a fair explanation of the procedure and data collection methods to be followed, including identification of any procedure which is experimental
 - 3. a description of any attendant discomfort and risks reasonably to be expected;
 - 4. a description of any benefits reasonably to be expected;

5. an offer to answer any inquiries concerning the procedures;
6. an instruction that the subject is free to withdraw his consent and to discontinue participation in the research project at any time without affecting the services (s)he is receiving from the participating senior center;
7. an explanation of how to file a grievance;
8. safeguards for the maintenance of confidentiality, including the appropriate procedures set forth by the Privacy and Confidentiality Regulations of the Executive Office of Elder Affairs;
9. disposition of the data at the termination of the project;
- (j) type of final product to be expected, intended use and manner of dissemination or publication;
- (k) where applicable, disclosure of intent to establish copyright, patents, or any other rights to the product and disclosure of organization or persons in whom such rights are to be vested; and
- (l) safeguards for the protection of the health and physical safety of clients; protection of client confidentiality and privacy; preservation of clients' dignity; to insure that clients are free from undue discomfort, distress and deprivation; and to insure equal treatment of clients without discrimination.

5. Evaluation of Proposals

- (1) The Elder Rights Review Committee shall review all proposals submitted pursuant to section 4.
- (2) In evaluating proposals the Committee shall utilize:
 - (a) available research experience and expertise;
 - (b) existing knowledge of research findings that bear upon the particular project under consideration;
 - (c) standards and canons of professional conduct and ethics;
 - (d) existing state and federal statues, regulations and guidelines, and
 - (e) existing research methods and procedures that have been established through rigorous standardization procedures and prescribed by recognized professional agencies or societies.
- (3) The Committee may reject proposals for any of the following reasons:
 - (a) the proposal involves more than minimal physical or psychological risks;
 - (b) there is no reasonable expectations of either direct or indirect improvement in the health, safety or welfare of elders;
 - (c) the grantee, subgrantee, contractor or subcontractor through which the proposal seeks access to clients of the Executive Office of Elder Affairs, does not consent to the proposal; and

(d) the existence or risk thereof of undue pressure upon individuals to participate in the project, including the use of coercive measures, including, but not limited to, peer pressure and coaxing, to enlist the participation of clients of the Executive Office of Elder Affairs.

6. Recommendations to Secretary

Upon reaching a decision on a proposal, the chairperson of the Committee shall forward the Committee's decision to the Secretary for his final decision.

7. Notification and Reconsideration

(1) The Secretary shall send written notice of the decision to the researcher/investigator submitting the proposal. If a proposal is disapproved, given approval subject to conditions, or partially approved, the Secretary shall include the written notification of his decision, the reasons for the decision.

(2) Any researcher/investigator wishing to do so may seek reconsideration in writing within ten days of the receipt of the original decision. The Secretary may remand the proposal to the Committee for its reconsideration.

8. Confidentiality

No grantee, subgrantee, contractor, or subcontractor shall furnish names and other data concerning clients of the Executive Office of Elder Affairs to researcher/investigators without the client's consent in writing given pursuant to applicable Privacy and Confidentiality Regulations, 801 CMR 3.00 et seq., and EOEI PI-97-55.

9. Complaints

(1) Any client, grantee, subgrantee, contractor or subcontractor, aggrieved by the actions of any researcher/investigator may file a complaint with the Committee, through the ERRC Chair. Complaints shall set forth the underlying facts that give rise to the complaint.

(2) Upon receipt of a complaint, the Committee shall notify the researcher/investigator that a complaint has been received by the Committee.

(3) If the Committee determines that the complaint sets forth facts that amount to a violation of this Program Instruction or the terms of the researcher/investigator's approved proposal, it shall undertake an investigation. As part of its investigation the Committee shall afford the person filing the

complaint and the researcher/investigator the opportunity to present any relevant information to the Committee.

- (4) If the Committee determines that there has been a violation of the provisions of this Program Instruction or the terms of the approved proposal, it may:
 - (a) recommend that the Secretary impose additional conditions on the project;
 - (b) recommend that the Secretary suspend approval of the project pending further appropriate action; or
 - (c) recommend that the Secretary rescind approval of the project.
- (5) If the grievance sets forth facts alleging that conditions exist that threaten the health or physical or mental well-being of clients, the Secretary may order the immediate cessation of the project until the Committee has acted upon the complaint.
- (6) The Committee shall promptly notify the person filing the complaint and the researcher/investigator in writing of its decision and the reasons for the decision.

10. Monitoring

- (1) The Executive Office of Elder Affairs may, in its discretion, monitor ongoing projects.
- (2) Executive Office of Elder Affairs monitoring activities may include:
 - (a) interviewing responsible project staff or grantee, subgrantee, contractor or subcontractor staff;
 - (b) review of written reports and supporting documents; and
 - (c) on-site inspections and reviews including interviews with project participants.