SOUTH CAROLINA DEPARTMENT OF MENTAL HEALTH
Columbia, South Carolina

OFFICE OF THE STATE DIRECTOR OF MENTAL HEALTH DIRECTIVE NO. 896-10 (5-100)

TO: All Organizational Components

SUBJECT: Institutional Review Board – Policies and Procedures for the Protection of Human Research Subjects

POLICY:
The South Carolina Department of Mental Health recognizes the need for safeguarding the rights and welfare of research subjects. In accordance with Department of Health and Human Services regulations, the South Carolina Department of Mental Health has an established Institutional Review Board (IRB) which is charged with these responsibilities.

All research projects involving patients of SCDMH and/or its employees must have SCDMH IRB approval prior to implementation. This includes research resulting in data obtained from patients or employees, research using DMH data-bases and files, and research conducted through the auspices or name of SCDMH or any of its institutions.
A case study is a report of treatment, and, as such, usually does not meet the Common Rule definition of research (a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge). Case studies that are not considered research (see below) do not require IRB review and approval. Case studies that do not involve the receipt, disclosure or use of Protected Health Information, "PHI" (i.e., health information paired with identifiers such as name, SS#, DOB, address, etc.) do not require a signed "AUTHORIZATION TO DISCLOSE SCDMH PROTECTED HEALTH INFORMATION" or other privacy authorization to receive, disclose or use the non-PHI. Case studies that do involve the receipt, disclosure or use of PHI must be reviewed by the local Privacy Officer (and if the use involves computer PHI, it must also be reviewed by the local Security Officer) for applicable Privacy Practices and other requirements (see Privacy Practices Directive 837-03 and applicable Security Policies.) Regardless, all case studies must be reviewed by the applicable supervisor(s).

If any of the following is present, the activity is considered <u>research</u> rather than a case study if:

- Investigational drug(s) or device(s) are involved (off-label use of an approved drug or device for the sake of an individual patient does not constitute research).
- There is a clear intent before treating the patient to use systematically collected data that would not ordinarily be collected in the course of clinical practice in reporting and publishing the case study.
- There is a plan to perform the treatment on some individuals but not on others.
- There is intent to manipulate medications (even approved ones) to determine maximum effectiveness, or to test if they work consistently well.

- Extra tests are conducted for the sake of reportability.
- There is a protocol/study plan.
- Records or data sheets are maintained separate from clinical records (particularly with identifiers).
- The primary purpose is to answer a research question, not to provide care.
- There is a possibility that the treatment might yield a case series if it is effective in others (e.g., testing a hypothesis).
- There is intent to publish a report that is analytical not descriptive.

If the Case study has any of the above elements, it is considered research and will need IRB approval before it is conducted.

Exemptions: Routine program evaluation and quality improvement data analysis involving existing client/patient data is exempted from this policy unless it involves sensitive content material. The IRB will develop and publish specific guidelines differentiating program evaluation from research.

I. The SCDMH Institutional Review Board shall:

A. Determine whether subjects will be placed at risk, and, if risk is involved, whether:
   1. The risks to the subject are so outweighed by the sum of the benefit to the subject and/or the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks.
   2. The rights and welfare of any such subject will be adequately protected.
   3. Legally effective informed consent, unless specifically waived by the Board, will be obtained by adequate and appropriate methods.
B. Be composed of 5-16 members who are sufficiently qualified with varying backgrounds to review research proposals and ascertain the acceptability of proposals in terms of organizational commitments and regulations, applicable laws, and standards of practice. At-large community members will be selected to represent special interests of persons who may be particularly vulnerable in research studies such as children, prisoners, mentally disabled, and minority groups. All members will be appointed for renewable three year terms by the State Director of Mental Health, who may also appoint members to fill unexpired terms.
C. Conform all procedures and decisions to the Code of Federal Regulations (45 CFR 26) which governs IRBs and sets standards for the protection of human subjects from research risks. Each IRB member will complete a federal Department of Health and Human Services approved certification program for IRB members prior to assuming duties.
D. Permit or request researchers to appear before the Board for discussion.
E. Review each active project at least annually.

II. The SCDMH Office of Research Administration shall:

A. Provide an Administrative Officer to assist the Institutional Review Board. The Administrative Officer shall promptly report all known instances of non-compliance with SCDMH policies to the Chairman of the IRB.
B. Maintain all relevant records of the IRB for a period of three years. Individual project records will be maintained for three years following completion of the project.
C. Receive, edit, and distribute to each member of the Institutional Review Board all appropriate research projects, including changes, for review at least 7 days prior to the meeting of the Board.
D. Devise an appropriate coding, storage, and retrieval system for periodic review of all active projects by the Board, including changes in format or in personnel.
E. Promptly report to the SCDMH Director and the U.S. Secretary of Health and Human Services any serious or continuing non-compliance by investigators with the requirements and determinations of the IRB.
F. Create adequate linkages between the IRB procedures and requirements and the Department's HIPAA regulations to ensure the rights and privacy of personal health information of subjects involved in research.

III. Allegations of Research Misconduct

Depending on the nature of the allegation/concern, the IRB shall appoint an investigator or committee to conduct an investigation and report their findings and any recommendations to the full Board. Board can seek additional information and in all instances where the allegations/concerns appear to have merit, shall give the researcher an opportunity to respond before taking action. All allegations of misconduct in research, founded or not, will be submitted to the Office of Research Integrity annually as required by federal guidelines.

This policy conforms to "Code of Federal Regulations, Title 45, Part 46" on protection of Human Subjects from Research Risks. Failure to comply with policies and procedures, as outlined in this directive, may result in the termination of a research project, the withholding of funds, or appropriate disciplinary action.

This directive supersedes Directive No. 890-09.

John H. Magill, State Director

February 22, 2010