Policy #: DHHS-02-17

I. SUBJECT

Research Policy

The Department of Health and Human Services (the Department) shall comply with health information privacy and security requirements, as well as other applicable research protections, relating to the use or disclosure of confidential consumer information in the research context.

II. POLICY STATEMENT

It is the policy of the Department to protect the rights and welfare of Department consumers whose information is requested for use or disclosure in the research context, or who are asked to participate in research studies. The Department will comply with all applicable human subject research requirements and confidentiality laws consistent with this policy statement.

III. RATIONALE

The Department is required by a variety of legal mandates to protect the confidentiality of a consumer’s protected health information (PHI) or other confidential data (together, “PI”). Additionally, the Department is covered by a Federalwide Assurance that requires compliance with federal research requirements for the protection of human subjects.

IV. PROCEDURES

1. If Department staff members or others wish to participate in or conduct research with Department consumers or the Department’s consumer data, the following process must be followed:

   a. The applicable Department office, facility or program contact must first obtain the Investigator/Researcher’s protocol (research proposal with safeguards) for review.
b. The protocol (and approval, where applicable, from an Institutional Review Board (IRB) other than the Department’s IRB) must be submitted to the Department’s Director of Healthcare Privacy/Human Protections Administrator for recording.

c. The protocol (and approval, where applicable) will be submitted to the Department’s IRB for approval.

d. The Department’s IRB will respond by email with approval or disapproval of the protocol, or with acceptance/rejection of the prior IRB’s approval process.

e. The Department’s IRB will also determine whether the protocol amounts to “research” by the Department.

f. If the Department’s IRB accepts the outside IRB determination or determines that the Department is not engaged in research, then information may be disclosed to the investigator/researcher via the Department’s “Data Sharing and Protection Agreement” (attached and available online on the Department’s Privacy/Security intranet page under “Research”).

2. An MOU or letter of support is not sufficient foundation for the Department to disclose confidential consumer information for research purposes.

3. The Department’s Director of Healthcare Privacy and Human Protections Administrator should be consulted regarding any questions or concerns regarding this policy.

V. DISTRIBUTION

All Department employees via e-mail and posting on the Department intranet.

Date

Mary C. Mayhew
Commissioner