Health Care Agency **Behavioral Health Services** **Policies and Procedures**	Section Name: Sub Section: Section Number: Policy Status:	Administration HIPAA 04.05.01 ☐New ☒Revised

	SIGNATURE	DATE APPROVED
Chief of Operations Behavioral Health Services	_____	_____

SUBJECT:	Use and Disclosure of PHI for Research Purposes

PURPOSE:

To establish a policy and guidelines to ensure that any use or disclosure of protected health information (PHI) for research purposes is in compliance with all applicable laws and regulations.

POLICY:

BHS shall comply with all regulations regarding the use and disclosure of PHI related to experimental research.

SCOPE:

This Policy and Procedure pertains to Behavioral Health Services (BHS) staff and BHS consumers who have decided to be voluntary research participants.

REFERENCES:

45 Code of Federal Regulations § 164.502(d); §164.508; §164.512; §164.514; § 164.528

21 Code of Federal Regulations § 50.24

BHS P&P 02.05.01 Notice of Privacy Practices:
http://intranet.ochca.com/bhs/pap

DEFINITIONS:

Research activities carried out by Agency staff can be classified into one of two groups:

- those that are part of regular health care operations (*operations research*) and
- those that extend beyond normal health care operations (*experimental research*).

Most research activities conducted by Agency research staff (e.g., program evaluations, performance outcome monitoring and reporting) fall under normal health care "*operations research.*" These activities are compliant with the Health Insurance Portability and

Accountability Act (HIPAA) Privacy Rule as part of normal Treatment, Payment, and Operations (TPO) of the Agency provided the client has signed a Notice of Privacy Practice (NPP) Authorization.

The Privacy Rule creates equal standards of privacy protection for research governed by the existing Federal human subject regulations and research that is not covered by those regulations. A covered entity such as the County of Orange may always use or disclose for research purposes health information that has been de-identified (in accordance with 45 CFR 164.502(d), and 164.514(a)-(c) of the Rule) without regard to the provisions stated below.

Protected Health Information: (PHI) means individually identifiable health information usually transmitted by electronic media, maintained in any medium as defined in the regulations, or for an entity such as a health plan, transmitted or maintained in any other medium. It is created or received by a covered entity, and relates to the past, present or future physical or mental health or condition of an individual, provision of health care to an individual, or the past, present or future payment for health care provided to an individual.

Disclosure: means the release, transfer, provision of, access to, or divulging in any other manner of information outside the County's health care components.

Use: means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination or analysis of such information within the County's health care components.

Limited Data Set: is protected health information that excludes 16 direct identifiers of the individual, or of relatives, employers, or household members of the individual, as set forth in the § 164.514(e)(2).

Data Use Agreement: is an agreement to provide a limited data set that excludes individually identifiable information and provides guidelines regarding the recipient's use and further disclosure of data provided.

Research: means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Institutional Review Board (IRB): means an Institutional Review Board established in accordance with and for the purposes expressed in the Code of Federal Regulations whose primary purpose is to protect the health and privacy rights of human subjects.

PROCEDURE:

I. The guidelines and policies that follow, specifically apply to human subjects (i.e., research participants) involved in research activities that extend beyond the normal scope of health care operations.

   A. All "experimental research", as defined above, conducted within BHS shall be submitted for pre-approval to the Health Care Agency's Human Subjects Review Committee which functions as the County's Institutional Review Board (IRB).

B. The Human Subjects Review Committee has responsibility for insuring that experimental research procedures meet all legal and regulatory requirements, including those outlined under HIPAA.

C. Prior to releasing any information based on the experimental research, BHS staff shall consult with the Health Care Agency's Human Subjects Review Committee to ensure that such a release is consistent with regulatory requirements.