



Office of Regulatory Compliance

HIPAA Policy 1.4

Title: Data Gathered Prior to April 14, 2003

Source: Office of Regulatory Compliance

Prepared by: Assistant Vice Chancellor for Regulatory Affairs

Approved by: Vice Chancellor for Research

Effective Date: July 1, 2013

Replaces: 02/26/03

Applies: All UCD campuses

Introduction

Purpose

The purpose of this policy is to provide members of the UCD workforce with guidance regarding what is required in order to use or disclose PHI that was obtained prior to the April 14, 2003 HIPAA Privacy Rule compliance date.

Reference

45 C.F.R. § 164.532

Applicability

It is the responsibility of all members of the UCD workforce who wish to use or disclose PHI after April 14, 2003, which was obtained prior to April 14, 2003, to comply with the terms of this policy.

This policy applies to PHI that was obtained prior to the April 14, 2003 compliance date for the HIPAA Privacy Rule, but which is being used or disclosed after April 14, 2003.

Policy

This policy outlines the circumstances under which PHI in the possession of UCD before April 14, 2003 may be used on or after April 14, 2003 without a new authorization. The circumstances under which this type of PHI may be used on

or after April 14, 2003 depend on whether the PHI was obtained for the purposes of research or whether it was obtained for other purposes.

Procedures

1. Effect of Prior Legal Permission for Purposes Other Than Research.

The UCD may use or disclose PHI that UCD created or received prior to April 14, 2003, for use other than research if prior to April 14, 2003, UCD had in its possession an authorization or other legal permission. The authorization or other form of permission must specify the intended use or disclosure and shall contain no agreed-to restriction.

2. Effect of Prior Permission for Research.

The UCD may use or disclose for research, to the extent allowed by one of the following provisions, PHI that UCD created or received either before or after April 14, 2003:

- a. Prior to April 14, 2003, the UCD obtained any of the following:
 - i. A valid authorization or other express legal permission from the individual to use or disclose PHI for the research; or
 - ii. informed consent to participate in the research; or
 - iii. a waiver by COMIRB (or another IRB, if applicable) of informed consent for the research issued in accordance with applicable federal law, unless informed consent is sought on or after April 14, 2003 involving the same individual for whose consent the waiver was previously granted.
- b. Additionally, there must not be any agreed-to restriction contained in any of the above provisions.