

REQUIREMENTS FOR REMOVING IDENTIFIERS FROM RESEARCH INFORMATION / RECORDS / SAMPLES

To ensure that "de-identified" information/records/samples cannot be linked to the subjects from whom they were obtained, the following Identifiers of the Individual or of Relatives, Employers, or Household Members of the Individual must NOT be included in, or linked to, research information/records/samples for protocols that the MCO IRB has determined must be handled in an anonymous manner. The Identifiers listed below are defined in the Health Information Portability and Accountability Act (HIPAA). [NPRM - Federal Register: December 28, 2000 (Volume 65, Number 250); Modifications and Final Rule published August 14, 2002 (Volume 67, Number 157)]

Standard: Information/records/samples that do not identify an individual and with respect to which there is no reasonable basis to believe that the information/records/samples can be used to identify an individual may be deemed to be anonymous.

HIPAA - 45 CFR 160 and 164

§164.514(b)(2)

(i) The following identifiers of the individual or of relatives, employers, or household members of the individual, must be removed for information/records/samples to be deemed anonymous, i.e., "de-identified":

- (A) Names;
- (B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
 - (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
 - (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
- (C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
- (D) Telephone numbers;
- (E) Fax numbers;
- (F) Electronic mail addresses;
- (G) Social security numbers;
- (H) Medical record numbers;
- (I) Health plan beneficiary numbers;
- (J) Account numbers;
- (K) Certificate/license numbers;
- (L) Vehicle identifiers and serial numbers, including license plate numbers;
- (M) Device identifiers and serial numbers;
- (N) Web Universal Resource Locators (URLs);
- (O) Internet Protocol (IP) address numbers;
- (P) Biometric identifiers, including finger and voice prints;
- (Q) Full face photographic images and any comparable images; and
- (R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; **and**

(ii) [You] do not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

Full text of this portion of HIPAA regulation can be found at:
<<http://www.hhs.gov/ocr/hipaa/finalreg.html>>