

AGREEMENT NOT TO DISCLOSE IDENTIFYING INFORMATION OF DONORS OF HUMAN BIOLOGICAL MATERIAL

Definitions:

"PROVIDER INVESTIGATOR" shall mean an investigator who has obtained human biological materials for: (1) non-research (clinical diagnostic or treatment) purposes with appropriate informed consent of donors to utilize excess materials for research; or (2) research purposes pursuant to an IRB-approved research protocol:

"RECIPIENT INVESTIGATOR" shall mean an investigator who accepts human biological materials for research purposes from PROVIDER INVESTIGATOR.

PROVIDER INVESTIGATOR:

NAME: _____
(print or type name)

POSITION / TITLE: _____

INSTITUTION (If Not MCO): _____

IRB PROTOCOL #: _____ APPROVAL DATE ____/____/____.

RESPONSIBLE IRB: _____ FWA #: _____

RECIPIENT INVESTIGATOR:

NAME: _____
(print or type name)

IRB PROTOCOL NUMBER: _____

IRB PROTOCOL TITLE: _____

Provider Investigator and Recipient Investigator Agree As Follows:

If PROVIDER INVESTIGATOR possesses information which may be used to identify the donor of the human biological materials (see Page 2 for examples of such identifiers), PROVIDER INVESTIGATOR and RECIPIENT INVESTIGATOR hereby agree that neither PROVIDER INVESTIGATOR, nor any of his/her associates with access to said identifying information, will, under any circumstances, disclose said identifying information to RECIPIENT INVESTIGATOR, or any of his/her associates. Likewise, RECIPIENT INVESTIGATOR agrees that neither he/she, nor any of his/her associates, will request said identifying information from PROVIDER INVESTIGATOR or his/her associates.

We further agree that this agreement has no expiration date.

PROVIDER INVESTIGATOR Signature: _____ Date: _____

RECIPIENT INVESTIGATOR Signature: _____ Date: _____

EXAMPLES OF POTENTIAL IDENTIFIERS

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.

The Identifiers listed below are defined in the Health Information Portability and Accountability Act (HIPAA). [Federal Register: December 28, 2000 (Volume 65, Number 250)] [Rules and Regulations] [Page 82811-82829] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr28de00-36] [[pp. 82811-82829]]

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