**De-identified Human Subject Certification**

In order to be exempt from IRB review or HIPAA requirements, any data accompanying tissue, serum, data, etc. derived from human subjects must be de-identified (including any labels). It is important to note that even if you are receiving samples from outside the country, the privacy laws apply when the samples are received. This letter has been included with your MTA to make sure that the samples you are either requesting or sending out have been properly de-identified. If your research requires the use of identifiers listed below, please contact the IRB and submit the appropriate approval or waiver to your JHTT contact. For your convenience, PDFs of IRB letters are accepted.

Definition of De-Identified Data

**Identifiers That Must Be Removed to Make Health Information De-Identified[[1]](#footnote-1)**

(i) The following identifiers of the individual or of relatives, employers or household members of the individual must be removed:

(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; and

(ii) The covered entity does 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.

I have read the above and certify that the materials involved in IRB/MTA #A\_\_\_\_\_\_\_ are de-identified as defined in this document. If they are not, I have attached the appropriate IRB form / letter:

## Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. See http://irb.jhmi.edu/HIPAA/deidentifieddata.html [↑](#footnote-ref-1)