UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER INSTITUTIONAL REVIEW BOARD NHSR STATUS FOR THE USE OF SELECTED COMMERCIAL VENDORS AND SPECIMEN & DATA REPOSITORIES

I. PURPOSE

To document the procedures used by University of Tennessee Health Science Center Institutional Review Board to determine whether the research use of selected specimen and data repositories qualifies for "not human subjects research" (NHSR) status and therefore does not require IRB review.

II. SCOPE

This SOP applies to the IRB administrative staff, Board members, and investigators.

III. BACKGROUND

Under the provisions of 45 CFR 46.102(e)(1) (45 CFR 46.102(f) in the previous Common Rule), federal regulations for the protection of human subjects are only applicable to "human subjects" as defined therein. Research using specimens or private information regarding individuals does not involve "human subjects" provided that all such individuals are deceased or the identity of the individuals is "not readily ascertainable" by the investigator.

Although the regulations for the protection of human subjects do not further clarify the conditions under which the identity of individuals is not "readily ascertainable," the HIPAA regulations have provided a commonly recognized standard for specifying the conditions under which private information has been altered in a manner that does not permit the identity of individuals to be readily ascertained. The latter situation applies when private health information about persons has been de-identified, i.e., stripped of 18 categories of identifiers enumerated in the HIPAA regulations. In accord with this standard, data transmitted to investigators in a de-identified form does not allow the investigator to "readily ascertain" the identity of individuals. Consequently, utilization of these materials in human research does not constitute the use of "human subjects' under the regulations.

Some databases or some commercial vendors may contain specimens and/or private health information that are labeled with a code. When repository materials are labeled with a code, it is possible to link the materials with identifiable individuals through the master key that correlates codes with the identity of persons. Whether research utilizing such materials constitutes the use

of "human subjects" under the regulations will depend on the form in which they are provided to investigators. If investigators are provided with a "limited data set" in which 16 categories of direct identifiers have been removed and investigators are prohibited from any access to the master key for any coded materials, then the identity of subjects is not "readily ascertainable" and the research does not involve "human subjects" as defined in the regulations.

Numerous research databases exist, and specific commercial vendors may sell materials, that contain only specimens or data that derive from deceased individuals, or that have been de-identified, or that are only shared with investigators in the form of a limited data set and without access to a master key. Because research use of a repository having one of these properties does not involve the use of "human subjects" as defined in the regulations, the regulations will not apply to any research use of materials contained in that repository. Consequently, in order to ease the paperwork burden associated with the research use of these repositories, the IRB has given "not human subjects research" (NHSR) status to the use of specific repositories that have been structured to have one of these properties. This NHSR status applies only to specific, designated repositories and commercial vendors that have been certified by the IRB to meet the conditions for NHSR status and whose names are listed in the policy below.

In Accordance With:

For studies approved under the revised Common Rule:
45 CFR 46.102(e)(1)

For studies approved under the Pre-2018 Common Rule:
45 CFR 46.102(f)

Research Using Human Specimens, Cell lines or Data
http://grants.nih.gov/grants/policy/hs/specimens.htm

Human Subjects Research – Human Specimens, Cell Lines or Data FAQs
http://grants.nih.gov/grants/policy/hs/faqs_specimens.htm

Compliance with this policy also requires compliance with state or local laws or regulations that provide additional protections for human subjects.

IV. DEFINITIONS

Coded data means (a) the data and/or biospecimens are labeled with a number, letter, symbol or combination thereof; and (b) a master key exists to decipher the

code, enabling linkage of the code to information that identifies the individuals from whom the data or biospecimens derive.

De-identified data means that the source material does not include any of the following 18 categories of personal identifiers of individuals, or of the relatives, employers or household members of such individuals:
(1) names;
(2) all geographic subdivisions smaller than a state, including street address, city, county, precinct, and their equivalent geocodes, except for the initial three digits of a zip code if the geographic unit represented by these three initial digits contains more than 20,000 people;
(3) 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 indicative of age over 89, except that such ages and elements may be aggregated into a single category of age 90 or older;
(4) telephone numbers;
(5) fax numbers;
(6) electronic mail addresses;
(7) social security numbers;
(8) medical record numbers;
(9) health plan beneficiary numbers;
(10) account numbers;
(11) certificate/license numbers;
(12) vehicle identifiers and serial numbers, including license plate numbers;
(13) device identifiers and serial numbers;
(14) web universal resource locators (URLs);
(15) internet protocol (IP) address numbers;
(16) biometric identifiers, including finger and voice prints;
(17) full face photographic images and any comparable images; and
(18) any other unique identifying number, characteristic, or code.

Limited data set means that the material provided to the investigator does not include any of the following categories of personal identifiers of individuals, or of the relatives, employers or household members of such individuals:
(1) names;
(2) postal address information, other than town or city, state, and ZIP Code.
(3) telephone numbers;
(4) fax numbers;
(5) electronic mail addresses;
(6) social security numbers;
(7) medical record numbers;
(8) health plan beneficiary numbers;
(9) account numbers;
(10) certificate/license numbers;

(11) vehicle identifiers and serial numbers, including license plate numbers;
(12) device identifiers and serial numbers;
(13) web universal resource locators (URLs);
(14) internet protocol (IP) address numbers;
(15) biometric identifiers, including finger and voice prints; or
(16) full face photographic images and any comparable images.
Individually identifiable means the identity of the subject is or may be readily ascertained by the investigator or readily associated with the information or biospecimens provided to the investigator.

Readily ascertainable means that the investigator has access to direct identifiers (e.g., names or social security numbers), codes and master keys, or other information that would enable the investigator to identify individuals whose private information or biospecimens are used in research.

V. PROCEDURES

1. UTHSC investigators may undertake a currently proposed study utilizing specimens or data from select repositories and select commercial vendors without undertaking any interaction with the IRB, provided that the IRB has previously certified that the following conditions are satisfied for all specimens and data available from the repository or commercial vendor:

   (a) the specimens and data were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals;

   (b) the ONLY research procedures in the currently proposed study involves the use of human materials from the repository/vendor; **AND**

   (c) all specimens or data are from deceased individuals; **OR**

   all specimens and/or data are **EITHER**

   de-identified; **OR**

   specimens and/or data in the repository are always transmitted to investigators in the form of a limited data set, and a data use agreement has been accepted under which the investigator cannot access direct identifiers (e.g., names or social security numbers), codes and master keys, or other information that would enable the investigator to identify individuals whose private information or biospecimens are used, and the investigator agrees not to attempt to re-identify individuals whose materials are transmitted to the investigator.

2. At the current time, the following specimen and/or data repositories and the use of the following commercial vendors have been certified by the IRB to meet the conditions for "not human subjects research" (NHSR) status and therefore do not require IRB review:

   Accegen Biotechnology

   American Diabetes Association, GENNID (Genetics of non-insulin dependent diabetes mellitus, NIDDM) Study (Corriel Institute)

   American Time Use Survey (ATUS)

   American Type Culture Collection (ATCC)

   Astarte Biologics

   Cell Applications, Inc.

   Cell Systems

   Centers for Disease Control and Prevention (CDC) Cell and DNA Repository (Corriel Institute)

   Cerner Health Facts Database (USA)

   Commission on Cancer's (CoC) National Cancer Data Base (NCBD)

   Consortium on Safe Labor (CSL)

   Cooperative Human Tissue Network (CHTN) (National Cancer Institute)

   Creative Bioarray/Creative Biolabs

   Cure Huntington's Disease Initiate (CHDI) Repository (Corriel Institute)

   Current Population Survey (CPS)

   Health Services Research Network (HSRN) Data Brief: National Disease and Therapeutic Index

   Health Services Research Network (HSRN) Data Brief: National Prescription Audit

Health Cost and Utilization Project (HCUP) Kids' Inpatient Database (KID)

Health Cost and Utilization Project (HCUP) National Electronic Injury Surveillance System (NEISS)

Health Cost and Utilization Project (HCUP) National Inpatient Sample (NIS)

Health Cost and Utilization Project (HCUP) Nationwide Emergency Department Sample (NEDS)

Health Cost and Utilization Project (HCUP) Nationwide Readmissions Database (NRD)

Health Cost and Utilization Project (HCUP) State Ambulatory Surgery and Services Database (SASD)

Health Cost and Utilization Project (HCUP) State Emergency Department Database (SEDD)

Health Cost and Utilization Project (HCUP) State Inpatient Database (SID)

Horizon

Human Biological Data Interchange (HBDI) Catalog (Corriel Institute)

Integrated Primate Biomaterials and Information Resource (IPBIR) Repository (Corriel Institute)

Lonza Inc

Millipore Sigma

National Eye Institute Age-Related Eye Disease Study (NEI-AREDS) Genetic Repository (Corriel Institute)

National Health and Nutrition Examination Survey (NHANES)

National Human Genome Research Institute (NHGRI) Sample Repository for Human Genetic Research (Corriel Institute)

National Institute of General Medical Sciences (NIGMS) Human Genetic Cell Repository (Corriel Institute)

National Institute of Neurological Disorders and Stroke (NINDS) Human Genetics DNA and Cell Line Repository (Corriel Institute)

National Institute on Aging (NIA) Aging Cell Repository (Corriel Institute)

National Disease Research Interchange (NDRI)

National Surgical Quality Improvement Program (NSQIP)

Public Health England

Surveillance, Epidemiology and End Results Program (SEER)

The Autism Research Resource (Corriel Institute)

The Cancer Genome Atlas (TGCA) (National Cancer Institute)

The Wistar Institute (Corriel Institute)

ThermoFisher Scientific

US Immunodeficiency Network (USIDNET) Repository (Corriel Institute)

3. Use of de-identified or coded data/specimens from sources other than the above-listed specimen/data repositories or commercial vendors must be submitted for IRB review and approval using the IRB application process, so that the IRB can confirm that the conditions for non-applicability of the regulations are satisfied. See *SOP: UTHSC IRB NHSR or Exempt Status: Determination.*

4. Use of individually identifiable data and/or specimens must undergo review and approval using the IRB application process via iMedRIS. See *SOP: UTHSC IRB NHSR or Exempt Status: Determination*, and *SOP: UTHSC IRB Expedited Review*.