***North Texas Regional Institutional Review Board (IRB)***

**IRB Project # \_\_\_\_\_\_\_\_\_\_\_** (Office Use Only)

**Request for Review of EXISTING Data Set (EXEMPT Category Research Project)**

**ALL research involving human subjects requires review and approval by the North Texas Regional Institutional Review Board (IRB).** Some research projects involving Existing data sets may be “exempt” from IRB Review and thus qualify as “Exempt Category” research. To determine if your research project is in this category, provide information using the following form. Please submit this form in IRBNet (www.irbnet.org). Note that evidence of Human Subjects Research Training for all study personnel must also be submitted or linked in IRBNet. Also, incomplete applications and supporting documentation will delay review and approval of this project. Additionally, the Principal Investigator must have full access to the IRBNet protocol package in order for it to be reviewed. If it is determined that your research project is NOT Exempt research, you will need to submit the project for review as an Expedited or convened (Full Board) protocol.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PROJECT INFORMATION**

*Title of Research Activity:*

*Name of Principal Investigator (Faculty/Staff Member):*

*Department/Program:* *Institution:*

*Contact Information - Phone:* *Email:*

*Other Persons Engaged in Research with this Data Set:*

##### Research projects involving analysis of secondary data may be considered as EXEMPT category research if:

1.   The data set(s) is (are) published and publicly available without restriction (e.g., data are published by a reputable source in a publicly-available journal, textbook or web-site) and neither the researcher nor any collaborating researcher on the project(s) has access to links that would connect the data to identifiable individuals, OR

2.    The data set(s) is (are) publicly available to researchers and others, but the data holder requires a “responsible use statement” or similar attestation to ensure appropriate use and protection of the data.  Neither the researcher nor any collaborating researcher on the project can have access to any links that would connect the data to the individuals from whom they were derived, nor may any researcher on the project attempt to re-identify any person from whom the data were derived.

 [Any questions regarding whether a data set meets these requirements should be referred to the Office of Research Compliance (ORC) – North Texas Regional IRB.]

***Note*: Research projects that merge more than one dataset in such a way that individuals may be identified are not covered by this policy and application, and *will require prior IRB approval.***

*List of Approved Publicly Available Datasets*

On Page 2 of this Form is a list of publicly available datasets/services that meet the requirements of the North Texas Regional IRB Existing Publicly Available Datasets Policy, in which data in these publicly available datasets have been stripped of identifiers. As a result, research using these data sets (or subset portions of them) does not rise to the level of “human subject research,” and does not require further review other than this Form.

If the research study does NOT involve one of these listed datasets, an application for IRB review MUST be submitted. [To add a publicly available dataset to the approved list, submit a request to the Office of Research Compliance – North Texas Regional IRB for consideration along with a link to the dataset.]

**SIGNATURES AND ASSURANCE** Signature certifies that the Principal Investigator understands and accepts responsibility to ensure that this research and the actions of all project personnel involved in conducting the study will conform to the North Texas Regional IRB approved protocol, all required institutional requirements/policies and procedures, and all applicable federal regulations.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PRINCIPAL INVESTIGATOR Signature Print Name Date

**The data set to be studied under this protocol is one (or more) of the following Data Sets or is available through one of the organizations listed below (check each as applicable):**

[ ]  [Autism Brain Imaging Data Exchange (ABIDE)](http://fcon_1000.projects.nitrc.org/indi/abide/)

[ ]  American College of Surgeons National Trauma Data Bank (NTDB)

[ ]  American College of Surgeons National Surgical Quality Improvement Program( ACS-NSQIP)

[ ]  Behavioral Risk Factor Surveillance System (BRFSS; public data only)

[ ]  [Better Access to Data for Global Interdisciplinary Research (BADGIR)](http://nesstar.ssc.wisc.edu/index.html)

[ ]  British Household Panel Survey

[ ]  Childhood Cancer Survivor Study (CCSS)

[ ]  Cornell Institute for Social and Economic Research (CISER)

[ ]  German Socio-Economic Panel Survey

[ ]  Healthcare Cost and Utilization Project (H-CUP) healthcare databases (NIS, KID, SID, SASD, SEDD)

[ ]  HIV Prevention Trials Network D01: Vaccine Preparedness Study/Uninfected Protocol Cohort – 4 files

[ ]  [Minnesota Population Center data sets (IPUMS, IHIS, ATUS-X)](https://international.ipums.org/international/)

[ ]  Inter-University Consortium for Political and Social Research (ICPSR)

[ ]  Luxembourg Income Study Project Archive

[ ]  Medical Expenditure Panel Survey (MEPS)

[ ]  National Child Development Study (all files)

[ ]  National Center for Health Statistics

* + NHANES: National Health and Nutrition Examination Survey
	+ NHCS: National Health Care Survey
	+ NHIS: National Health Interview Survey
	+ NIS: National Immunization Survey
	+ LSOAs: Longitudinal Studies of Aging
	+ NSFG: National Survey of Family Growth
	+ SLAITS: State & Local Area Integrated Telephone Survey
	+ Vital Statistics: National Vital Statistics System

[ ]  National Collegiate Athletics Association (NCAA) Injury Surveillance Program (ISP)

[ ]  National Election Studies

[ ]  National Epidemiologic Survey on Alcohol and Related Conditions (NESARC)-Wave 1 & Wave 2

[ ]  National Hospital Ambulatory Medical Care Survey (NHAMCS)

[ ]  National Longitudinal Study of Adolescent Health (Add Health)

[ ]  National Longitudinal Surveys (NLSY)

[ ]  National Survey of Children’s Health (NSCH)

[ ]  National Survey of Children with Special Health Care Needs (NS- CSHCN)

[ ]  Panel Study of Income Dynamics (PSID)

[ ]  Survey data publicly available through the Roper Center for Public Opinion

[ ]  Survey of Consumer Finances (SCF)

[ ]  Survey of Consumers (SCA)

[ ]  University of Michigan Health and Retirement Study (HRS) [Unrestricted data sets only]

[ ]  [University of Wisconsin-Madison Data and Information Services Center (DISC)](http://www.disc.wisc.edu/)

[ ]  U.S. Bureau of the Census

[ ]  U.S. Bureau of Labor Statistics

[ ]  Other Data Set Not Listed Above (complete information below):

**Complete this section below ONLY if requesting use of a dataset not listed above:**

Source of data:

Were the data originally collected for research purposes: **Yes** [ ]  **No** [ ] If yes, by UNTHSC researchers? **Yes** [ ]  **No** [ ]

Is the Source “publicly available”? **Yes** [ ]  **No** [ ]

Note that “Publicly available” means that the general public can obtain the data. Sources are not considered “publicly available” if access is limited ONLY to researchers. ***NOTE: You must submit a copy of the catalog page/ website page indicating where the dataset can be obtained or located.***

**Does this dataset contain personal identifiers?**  **Yes** [ ]  **No** [ ]

If Yes, what is/are the identifier (i.e., name, SSN, address, medical record number, etc.):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_