



# MCW Office of Research Standard Operating Procedure

## PUBLIC DATA SETS

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Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

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### **PURPOSE:**

Research using certain publicly available data sets does not constitute human subjects research because the data contained within these specific data sets do not meet the federal definition of "human subject."

### **DEFINITIONS:**

**Public Data Sets:** Collections of data that have been made publicly available.

- Includes files consisting of medical and/or research data prepared with the intent of public use.
- Includes data files that have been reviewed under the jurisdiction of an IRB with the intent of making them available for public use. The federal government has responsibility for the review of federal statistical data collections.
- Does not include data shared informally among colleagues.

**Publicly Available:** Material is widely available, even when:

- Identifiers are included, so long as individuals whose data is represented would not reasonably expect data to not be made public.
- A fee is charged for obtaining the data.
- Access to the data is limited to researchers, if any researcher with a standard academic or research affiliation has access.

**Restricted Use Data Sets:** Not considered publicly available.

- Files upon which use restrictions are imposed and access is limited to those who sign any necessary agreements to receive the data under these restrictions. These may be distributed by governmental agencies, research organizations, and others.

### **PROCEDURE:**

When seeking access to any data set, the investigator must pay close attention to how the data set is described by the supplier. A supplier may have the ability to provide different aspects of the same general data as both as a public data set (e.g. a research data set which has been stripped of identifiers) and a restricted use data set (e.g. that same data set is provided with identifiers).

### **MCW List of Data Sets Considered Public**

The HRPP Office maintains on its website a current list of data sets it considers to be public which do not require MCW IRB submission. Researchers may utilize these data sets without submitting an IRB application if the **only** research activity is the use of one of these data sets.

If a data set is not featured on this list, the investigator should submit an IRB application via eBridge. If the investigator wishes to propose that a data set be added to this list, see instructions below under “Adding to the list of data sets considered public.”

### **IRB Staff Review**

1. An IRB application must be submitted in eBridge when:
  - a. The data set is not listed on the IRB website as a public data set.
  - b. The data set is listed on the IRB website as a public data set but a third party requires documentation from the IRB confirming that the use of this data does not constitute human subjects research.
  - c. Data from multiple public data sets are merged, as this may alter the nature of one or both sets (e.g. two de-identified data sets could be merged to create an identifiable data set).
  - d. Investigator seeks to enhance a public data set with identifiable or potentially identifiable data.
  - e. Data sets which are not publicly available are used alongside publicly available data sets.
  - f. Activities interacting or intervening with human subjects are proposed in addition to use of publicly available data sets.
  - g. Using controlled-access data sets from the NIH dbGaP data repository.
  - h. The investigator plans to create a public data set by preparing files with the intent of making them available for public use.
  
2. The data supplier may require the researcher or researcher’s institution to sign a Data Use Agreement that explicitly requires IRB approval or a determination of exempt status. If IRB review is required:
  - a. Complete and submit an IRB application in eBridge.
  - b. Upload a copy of the Data Use Agreement to the application. An unexecuted copy is acceptable.

### **Adding to the list of data sets considered public**

1. A data set may be nominated for inclusion on the MCW List of Data Sets Considered Public by completing and submitting the Public Data Set Nomination Checklist.
  - a. The IRB does not include data sets that directly or indirectly identify subjects on this list.
2. The nominated data set and documentation provided to the MCW IRB will be reviewed by the HRPP Office.
3. Written notification of the review outcome will be provided to the individual who submitted the nomination request.
4. If the data set is found eligible, the data set will be added to the MCW List of Data Sets Considered Public.

### **REFERENCES:**

N/A

**SUPPORTING DOCUMENTS:**

MCW List of Data Sets Considered Public

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