elements such as race, age bracket and sex that may allow someone to identify a person from a dataset even without having access to direct identifiers.

Note 1: The answer to this question should be "yes" if the investigator can readily ascertain the identity of the individual(s) to whom the identifiable private data pertains. The answer should only be "no" in cases where the investigator does NOT have access to the key under ANY circumstances, until the individual(s) is/are DECEASED. For example, (1) the investigator and

The UNG IRB Position Dealing with Existing Data Sets

Existing Data Sets: Option 1

De-identified data - whether publicly available or accessible through data use agreements – do not constitute human subjects research as defined at 45 CFR 46.102. UNLESS a project merges multiple data sets and in so doing enables the identification of individuals, the project **does NOT require IRB review**. Many studies utilize data made available through large data consolidation bureaus and consortiums. Here is a list of data holders whose archives include publicly available, de-identified data.

1. Inter-

4. description of data security and access procedures to be implemented (including any requirements required by the data holder.

References

• The Common Rule 45 CFR 46: