1.0 Purpose
The purpose of this SOP is to describe the use of Limited Data Sets.

2.0 Policy

It is the policy of the IRB that the use of Limited Data Set will be in full accordance with regulations at Health and Human Services 45 CFR §46.

2.1 A researcher with IRB approval and a Data Use Agreement between the researcher and the covered entity can use and disclose Protected Health Information that contains a Limited Data Set without a HIPAA authorization or a waiver of consent granted by the IRB.

The limited data set must have all the identifiers removed, except the following:

A. A unique identifying number, characteristic or code (e.g., a registry or study number).

B. Elements of dates (e.g., birth).

C. Town, city, state, and ZIP code.

2.2 One of the advantages associated with the use of a Limited Data Set is that it is not subject to the HIPAA requirements of accounting for disclosure of Protected Health Information. Additionally, the limited data set also allows the maintenance of a linked code, which permits re-identification of an individual in the future should the need arise. However, the investigator who is using the Limited Data Set cannot maintain the linked code. The Director will maintain such codes.