Guidance for Developing IRB Protocols Approved under the Unit Data Guidelines

adapted from the Institute of Medicine (US) Committee on Data Standards for Patient Safety[1]

Data standards are a critical informatics component necessary for an accurate and safe information flow. With common standards, student and employee data housed in the student information system and other UNC official systems of record can be accurately collected and subsequently protected. Common data standards also support common understanding of data elements crucial to the production of rigorous research. This document provides information on data standards as they relate to projects approved through the Unit Data Guidelines procedures.

DEFINITIONS

Aggregate data – data where individual records are not separated, and information is compiled and summarized.

Assessment – as defined by Marchese, 1987, "Assessment is the systematic collection, review, and use of information about educational programs undertaken for the purpose of improving student learning and development".

Quality Improvement – systematic methods used to gain learning and knowledge for the continual improvement of a product, service, or process.

Research - as defined by 45 CFR §46.102 "Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge".

Unit Data – Data at the individual, or student level.

DATA STANDARDS

Data standards encompass methods, protocols, terminologies, and specifications for the collection, exchange, storage, retrieval, and destruction of information associated with research and quality improvement project using data extracted through the guidelines discussed above. Unit data requests for operational processes will be forwarded to Business Intelligence and Data Engineering (BIDE).

Requests requiring extraction of unit data for research and/or non-operational quality improvement will be directed to the Office of Institutional Research and Effectiveness (OIRE) and MUST have a protocol that has been approved by the UNC IRB. NOTE: as part of the current IRB application, any application that requires OIRE resources to extract data must discuss with the Director of OIRE prior to protocol approval. The Director will assist

the requestor in following [Unit Data Guidelines](#) procedures. For each project, the following standards must be addressed:

- *Data elements and definitions of those elements*—determination of the data content to be extracted. The protocol must specify and define each data element requested.

- *Data and file formats*—standard formats for electronically encoding the data elements to be extracted. The protocol must specify the format in which the data elements will be extracted and in which file format it will be delivered (e.g. XLSX, CSV, DAT, TXT, etc.)

- *Data and file encryption* – standard methods for electronically protecting the data elements to be extracted. Data will be shared via a secure UNC Sharepoint folder. If this is not possible, the protocol must specify how the data will be securely transmitted and encrypted.

- *Data storage* – The protocol must specify how the researcher will secure the data, and it must be in compliance with best practices in securing stored data (e.g. encrypted file, in a specified sharepoint environment, etc.).

- *Data usage* – The protocol must specify how the data will be used and who will have access to use the data. The requestor must acknowledge and affirm that only those outlined in the protocol as using the data will have access to the data. The requestor must affirm the data will not be used for purposes other than what is approved in the protocol.

- *Data destruction* – following institutional policies for data security, the protocol must outline written assurances of how data will be destroyed upon completion of the project.

Unit data for research and non-operational quality improvement will only be provided as outlined in the Unit Data Guidelines once all data standards have been addressed and approved in an IRB Protocol. In the event that a data standard within an approved protocol has been found to be incomplete or call into question what is being asked, the requestor will be directed to modify the protocol for clarification.

CONSEQUENCES OF NON-COMPLIANCE OR MISUSE

Failure to follow approved protocols constitutes [research misconduct](#) and violations will be handled in accordance with established procedures. Additionally, access to unit data related to the violated protocol will be immediately removed by OIRE.