ICDB Clinical Review Committee
May 12, 1995

1.0 Purpose

As a result of the first round of data quality site visits to each of the ICDB Clinical Centers during 1994-95, a number of protocol violations and serious data quality problems were identified. Based on the recommendations of the Site Visit Team, the NIDDK staff took action to remove selected patients from further follow-up and an official letter from the NIDDK Project Officer was sent to each of the PIs summarizing these decisions.

In order to assist the NIDDK staff in such decisions in the future, a Clinical Review Committee will be appointed. The duties of this committee are to review the details surrounding any **future** recommendations to withdraw a patient from further follow-up due to confirmed protocol violations and/or serious data quality problems.

2.0 Membership and Policy

The NIDDK Project Officer will appoint a Clinical Review Committee, composed of three physicians (must be either a Principal Investigator or Co-Investigator of one of the funded ICDB Clinical Centers) and one Research Coordinator. Ex-Officio members will include NIDDK Project Staff and Data Coordinating Center (DCC) Staff.

Majority vote (3 of 4) among the four voting members will be required to recommend a patient for withdrawal from further follow-up. The DCC Staff will present the evidence to the committee for their deliberations, based on information assembled at the DCC, and the NIDDK Project Staff will authorize final actions to be taken on each case.

This Clinical Review Committee will meet quarterly if needed, typically using the mechanism of a telephone conference call, to review materials submitted by the DCC in advance.

3.0 Protocol Monitoring

Ensuring high data quality and adherence to the ICDB protocol continues to be the responsibility of the Clinical Center staff, and ultimately of the PI. However, the DCC will continue to implement minimal protocol monitoring designed to detect potential problems, and will be alerting the NIDDK Project Officer of these selected potential problems on a quarterly basis. Depending on the nature of the problems, a Site Visit may be authorized to either confirm or resolve the problems detected at the DCC. It will be the responsibility of the DCC to alert the NIDDK Project Officer of any problems which can be detected, as described in the May 4, 1995 memo on **ICDB DCC Protocol Violations Monitoring**. It will be the responsibility of the NIDDK Project Officer to call a meeting of the Clinical Review Committee as warranted.