1. PURPOSE

1.1 This document describes the Division of Microbiology and Infectious Diseases (DMID) requirement for using the DMID contracted Statistical and Data Coordinating Center (SDCC).

2. SCOPE

2.1 This policy applies to:

- Any clinical trials conducted under DMID-held Investigational New Drug Applications (IND) or Investigational Device Exemptions (IDE).
- Any non-IND clinical trials conducted under contract.
- Any non-IND clinical trials funded under cooperative agreement and implemented through a DMID funded network.

3. DEFINITIONS

3.1 The DMID SDCC is the vendor (company) that holds the primary Statistical and Data Coordinating Center contract from DMID.

For other definitions, see DMID glossary.

4. RESPONSIBILITIES

4.1 As delineated in the policy.

5. POLICY

5.1 All clinical trials conducted under a DMID-held IND or IDE must use the DMID SDCC for data management and statistical analysis of all primary and secondary endpoints.

5.2 For all non-IND clinical trials conducted under contracts, the decision to use the DMID SDCC or alternative DCC/SDCC will be made by the DMID SDCC Contracting Officer's Representative (COR) in consultation with either the Director of OCRR or the Associate Director for Clinical Research.

5.3 For all non-IND clinical trials funded under cooperative agreement and implemented through a DMID funded network, the decision to use the DMID SDCC or alternative DCC/SDCC will be made by the Program Officer (PO) in consultation with either the Director of OCRR or the Associate Director for Clinical Research.

5.4 For clinical trials that use the DMID SDCC (per 5.1-5.3), where the protocol includes exploratory endpoints:

5.4.1 Exploratory endpoint data that are not intended for submission to a regulatory authority (if explicitly stated in the protocol) do not need to be submitted to or analyzed by the DMID SDCC.

- The analysis can occur at the DMID SDCC or by another group
  - Request for analyses of large datasets such as genomics and transcriptomics at the DMID SDCC should first be discussed with the SDCC COR.

- Analyses of exploratory endpoints by other groups for a blinded clinical trial that require the use of unblinded or potentially unblinding data (e.g. randomization allocation, Pk data), the unblinded data cannot be sent to the group conducting the exploratory analysis until after the primary trial data lock.

5.4.2 Exploratory endpoint data that are intended for submission to a regulatory authority (or where the protocol is silent regarding intent to submit to a regulatory authority) will be submitted to and analyzed by the DMID SDCC.

5.5 This policy does not preclude other clinical trials and clinical studies not listed in 2.1 from using the DMID SDCC. The DMID SDCC may be used for these other trials with approval of the DMID SDCC COR.

5.6 Secondary research data (from Biospecimens for Secondary Research) do not need to be submitted to or analyzed by the DMID SDCC.

5.7 The DMID SDCC is the vendor that holds the primary Statistical and Data Coordinating Center contract from DMID. The use of this vendor through other funding mechanisms (e.g. other contracts or subcontracts) meets the intent of this policy.

5.8 Exceptions to the policy are allowed and require written justification and documented approval by either the Director of OCRR or the Associate Director for Clinical Research.

6. REFERENCES

Not applicable

7. APPENDICES

Not applicable

8. REVISION HISTORY

8.1 DMID-DM-POL-00001 rev 01, is the original version of this procedure within the eQMS. It replaces REG-Policy-004.

9. ADDITIONAL INFORMATION

9.1 Document Lead: Director, OCRR

9.2 Posting externally: Yes