1. PURPOSE

1.1 The purpose of this policy is to establish the standards for electronic signatures on documentation in the Sponsor files managed by the National Institute of Allergy and Infectious Diseases (NIAID) Division of Microbiology and Infectious Diseases (DMID).

2. SCOPE

2.1 This policy applies to documents utilizing electronic and/or digital signatures from either:

2.1.1 Clinical trials conducted under where DMID is the regulatory Sponsor for Investigational New Drug Application (IND)/Investigational Device Exemption (IDE) or equivalent.

2.1.2 Non-IND clinical trials and studies when DMID maintains the sponsor records.

2.2 This policy applies to both DMID staff and clinical research site staff.

3. DEFINITIONS

3.1 Electronic Signature is a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature (21 CFR 11.3(b)(7)).

3.2 Digital signature is an electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified (21 CFR 11.3(b)(5)).

3.3 Flattened digital signature occurs when a flattening pushes the appearance of the signature annotation into the page content effectively deleting interactive elements but retaining the visual appearance of those elements.

For other definitions, see DMID glossary.

4. RESPONSIBILITIES

4.1 As defined under Policy.

5. POLICY

5.1 Electronic signature methods acceptable by DMID (based on those acceptable by the US Food and Drug Administration) include:

5.1.1 Scanned signatures.

5.1.2 Digital signatures (e.g., signed with a Personal Identity Verification (PIV) card or using electronic signature platforms).

5.1.3 Flattened digital signatures including:

- The printed name of the signer.

- The date and time when the signature was executed.
- The reason or meaning for the signature (e.g., reviewer, approval, responsibility, or authorship).

5.2 Electronic signatures must be linked to the respective electronic record(s) to ensure that the signatures cannot be removed, copied, or otherwise modified to falsify an electronic record by someone other than the signer.

5.3 Electronic signatures from federal institutions must meet all applicable requirements under 21 CFR Part 11 Subpart C.

5.4 Electronic signatures within a federal agency should use a signature mechanism linked to the US government issued personal identity verification (PIV) or equivalent card.

6. REFERENCES

6.1 21CRF11

6.2 FDA: Important Information About Digital/Electronic Signatures, 03/21/2018

6.3 Part 11, Electronic Records; Electronic Signature – Scope and Application: Guidance for Industry (September 2003)

6.4 Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations Questions and Answers Guidance for Industry

7. APPENDICES

Not applicable

8. REVISION HISTORY

8.1 DMID-TD-POL-00002 rev 01 is the original version of this procedure within the eQMS.

9. ADDITIONAL INFORMATION

9.1 Document Lead: Office of Clinical Research Affairs (OCRA)

9.2 Posting externally: Yes