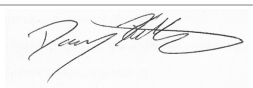
	Intermountain Forensics	SOP #	ADM-103
		Revision #	01
Forensic DNA Technical Leader Approval		Issue Date	
		6/1/20	

Documents

1. Purpose

This policy describes the document initiation, control, storage and retention in the laboratory.

2. Summary

This document describes how standard operating procedures (SOP's) are created and maintained, including logging revisions, control and change control of the document and logs. Secure storage, disaster recovery and retention requirements are also denoted.

3. Procedure

Standard Operating Procedures

1. The laboratories SOP's are controlled documents of the quality management system that provide policy information to staff, describe specific procedures to do day to day activities and records that are used as templates, logs and general forms to support activities and case files/reports.
    a. SOP's are organized by prefix designation and document number in a XXX-### format.
        i. Prefixes denote the function of the SOP document
            1. Administrative, Quality and Management System – ADM
            2. Organizational – ORG
            3. General Laboratory – LAB
            4. Evidence – EVD
            5. Serology – SER
            6. DNA Extraction – EXT
            7. DNA Quantification – QTY
            8. DNA Amplification – AMP
            9. Interpretation, Analysis and Comparison – IAC
            10. Documentation and Reports – DOC
            11. Maintenance – MNT
            12. Audits and Assessments - AUD
        ii. Document numbers reflect the type of document
            1. Policy level – 100-199
                a. Policies are high level directives on the overall operations of the laboratory
            2. Procedure level – 200-299
                a. Procedures are specific instructions on day to day activities
            3. Record level – 300-399
                a. Documents are forms, worksheets, logs, templates etc. that are used to document adherence to policies and procedures
    b. Revisions
        i. A revision number is assigned whenever a change to a document occurs.
        ii. Upon Forensic DNA Technical Leader approval of a replacement to an existing policy or procedure:
            1. The replaced document is saved to an "obsolete" folder
            2. The new document is transformed into a PDF using the same prefix and document number
            3. The Revision number is identified in the title at the end of the file name (e.g. EVD-200 (Rev2)
            4. The old revision is archived on the obsolete tab of the SOP Reference log (DOC-302)
                a. A summary of what has changed is added to highlight to staff what has changed
            5. The new revision is logged into the SOP Reference log (DOC-302) with the new revision number and date or approval
            6. Major changes will be announced to staff (e-mail, documented meeting etc.)
                a. Major change would entail fundamental scientific and or procedural changes
                    i. Examples: Using a new volume, changing duration of an incubation etc)
                b. Minor changes would comprise of administrative, organization or
                    i. Examples: Addressing typos, changing the format of the document etc.)

7. The Forensic DNA Technical Leader will determine whether the change is major or minor

2. SOP's that are deemed obsolete and/or any documents that are housed in the "obsolete" folder should not be used for active casework after the date that they were made obsolete

3. All SOP's will be locked for editing as a PDF file and all active SOP's will be utilized in PDF file format
    a. Editable documents are typically denoted as _RAW files and are stored in a separate file structure from active SOP's
    b. Any 100 or 200 level document must only be utilized in PDF form. RAW files will not be used as active SOP's for the laboratory

4. 300 level documents
    a. Any 300 level document is considered a "live" document. The active document will be maintained within the active documents folder structure, but will be maintained in editable format
        i. It is expected that modification to the 300 level document will occur and is only utilized as a template
        ii. These documents may be used as forms, logs and/or templates that will be edited as a result of day to day procedures (logs, document requests etc) and/or generation of data for the case file (tech review forms etc.)
5. Website transparency
    a. To promote maximum transparency finalized SOP's will be posted on the website for review, comments and feedback
    b. 100 and 200 level documents are required to be posted to the website
    c. This is recommended to occur within 30 days of the finalization of the SOP

Document Retention

6. All quality management documents including Standard Operating Procedures, audit documents and summaries, validation documentation and summaries, corrective action and preventative action documentation and training records will be maintained indefinitely.

7. Case files and reports will be maintained indefinitely.
    a. A copy of the report will be memorialized upon completion of the case (pre-review) and upon completion of the review (case finalized). These files will be maintained indefinitely.

8. Files utilized to create a case report (excel documents, statistics sheets) may be deleted upon completion of the case provided they are memorialized within the case file and/or laboratory report
    a. Raw GMIDx data files will be maintained with the case file
    b. GMIDx projects may be deleted upon the case finalization (provided all of the cases within the project have also been finalized

Document Security

9. All quality management documents, casefiles and reports are housed on a secure cloud based server using Microsoft Azure.
    a. The shared server may only be accessed by a restricted number of individuals maintained by the laboratory director (or designee)
    b. Network security is multi-level, always updated by the hosted solution and far more robust than traditional servers
10. Disaster recovery is maintained by Microsoft Azure and mirrored at multiple redundant sites to ensure data is never lost

4. References

https://azure.microsoft.com/en-us/overview/what-is-cloud-computing/#benefits

5. Definitions

GMIDx: Genemapper IDX analysis software