



BIOGENIX

CONFIDENTIALITY POLICY AND PROCEDURE

	NAME	DESIGNATION	SIGNATURE	DATE
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2. REVISION HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
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4. POLICY STATEMENT

The policy is implemented as per the following procedure

5. PURPOSE

To establish a procedure recognizing the patients and staff members right to privacy in relation to their record and to protect all information contained therein, written, electronic or verbal. It is primary concern that all Biogenix employees are aware of the importance of confidentiality and the types of information that are considered to be confidential. This procedure is as per clause no.4.1.1.3 of ISO 15189 standard for Medical laboratories Requirement for Quality and competence.

6. SCOPE

The procedure is applicable for maintaining confidentiality

7. DEFINITIONS

Patient confidentiality: Confidentiality is central to the trust between doctors and patients and an essential part of good care.

8. ACRONYMS

N.A.

9. RESPONSIBILITIES

- 9.1. Laboratory management.
- 9.2. Quality Department.
- 9.3. Team leader of each experimental group is responsible for supervising the laboratory behavior of group members.
- 9.4. All medical laboratory personnel.





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10. PROCEDURE

- 10.1. It is the responsibility of all staff to maintain the confidentiality of all medical, financial and administrative in addition to all other sensitive information that they may become aware of in the course of their duties.
- 10.2. All employees sign a statement of confidentiality before beginning their work at Biogenix lab.
- 10.3. Any employee who is proven to have breached the confidentiality procedure will be subject to disciplinary action, up to and including termination from employment.
- 10.4. All information per training to a laboratory investigation will be viewed as confidential, including:
 - 10.4.1. The patient's demographics, clinical status and history, whether accessed through the computer system or stated on laboratory requisition forms.
 - 10.4.2. All Laboratory results and reports in whatever form, including data retained on laboratory analyzers, internal worksheets and log books.
 - 10.4.3. All staff who view confidential patient information in the course of their work will not share this information with others, unless others need to know, and are authorized to receive the information for the performance of their duties.
 - 10.4.4. Under no circumstances laboratory staff gives, in any form, results or reports directly to patients, any patients requesting such information is referred back to their consulting physician or Laboratory Director.
 - 10.4.5. Those staff that have access to patient information through the computer system are to access only those records or information which they require for the performance of their duties. Browsing through patient records is strictly prohibited.
 - 10.4.6. All confidential laboratory documents and specimens are handled and stored in a manner that safeguards against access by non-authorized personnel, both inside the Laboratory and in the course of transferring material to and from the Laboratory.





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10.4.7. All documentation not required for permanent records will be destroyed in a manner which ensures confidentiality (i.e. shredder). Likewise, discarded specimens is removed for destruction in a manner that avoids any possibility of interception.

10.5. Security of Electronic Information

10.5.1. Laboratory director is responsible for determining and assigning appropriate access for BIOGENIX Staff to the Lab Information System modules pertaining to their departments.

10.5.2. Orientation regarding system access is provided prior to assignment of authorization privileges.

10.5.3. Those who have access to patient information through the computer are to access only those records or information, which they require for the care of their patients or the normal course of their duties. Browsing through patient records or accessing records that are not required is strictly prohibited.

10.5.4. LIS user I.D, passwords, or other types of authorizations are assigned on an individual basis and are not shared with others. Users are required to take all reasonable precautions to protect the privileges assigned to them.

10.6. Password control:

10.6.1. Password not easily guessed

10.6.2. Immediate change if suspected disclosure

10.6.3. Report of any suspected misuse by another individual

10.6.4. Appropriate logoff from the application(s)

10.6.5. Safeguarding information and resources which are available in the course of their job duties.

10.6.6. Each user is responsible to ensure that data, which resides within his/her work station, is safeguarded and protected from unauthorized access.

10.6.7. Each user is responsible to ensure log-off from the workstation when his/her work is complete and another user want to use the system or when leaving the workstation for a period of time.

10.6.8. Everyone is required to report to the IT person if any instance of improper or potentially illegal use of the electronic information system.

10.7. Removal of Access:

Laboratory Director ensures that:

10.7.1. Timely review of staff's access to systems is performed when job duties or assigned role is modified within the department.

10.7.2. Information Technology (IT) personnel delete access as soon as possible after receiving notification of separation or termination.





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10.8. Securing Information - Storage Media:

10.8.1. Access, retrieve, and communicate confidential or sensitive information is maintained

10.8.2. Are safeguarded against theft, tampering and unauthorized access.

10.9. Non-personal-identifiable information:

10.9.1. Is also be classed as confidential such as confidential business information e.g. financial reports; commercially sensitive information e.g. contracts, trade secrets, procurement information, which are also treated with the same degree of care.

10.10. Employees:

10.10.1. Printed reports for employees will be hand delivered in a sealed envelope to the Laboratory Pathologist.

10.10.2. **Privacy and confidentiality of staff member:** Staff members who through a third party or other means become aware of the identity of a colleague are positive for any infectious disease, required to respect the privacy and confidentiality of the affected staff member. Infected individuals as well as their families whose identity has been revealed through rumors and hearsay may suffer from stigmatization, causing them additional unnecessary distress. Staff members who have been identified as close contacts of an infected individual do not require to know the identity of that individual to protect themselves. They should follow the personal hygiene protective measures recommended. Personal details of infected individuals and their dependents must remain strictly confidential.

10.11. Copies of all associated laboratory documents are filed in the Laboratory separate from other documents.

11. CROSS REFERENCE

11.1. ISO 15189 Third Edition 2012-11-01 corrected version 2014-08-15, Medical laboratories- Requirements for quality and Competence

11.2. HAAD clinical laboratory standards version I.

12. RELEVANT DOCUMENTS & RECORDS





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12.1. BG/REC/GEN/008 Statement of Confidentiality Form.

