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# Personnel Management

## Policy

The Laboratory provides adequate resources to perform, verify, and manage all activitiesin the laboratory. The Laboratory strives to obtain and retain personnel who are the best prepared for the position and provide the highest quality services, using methods that meet or exceed the applicable legal and regulatory requirements. Where necessary, the Laboratory collaborates with Human Resources in these processes.

## Adherence to Management Policies

### It is the policy of this Laboratory to follow GENETWORx’ Personnel Policy regarding the following Laboratory Personnel Policies:

#### Confidentiality

#### Dress Code

#### Employee Handbook

#### Weather and Emergencies

#### Job descriptions

#### Performance Appraisal

#### Time and Attendance

## Policy

### This policy provides direction for the processes and procedures to effectively manage laboratory personnel.

### Responsibility:

#### The Human Resources Department is responsible for maintaining job descriptions, determining pay scale, posting job positions, recruiting for job positions, performing necessary employee health screening, and maintaining inclusive dates of employment.

#### The Laboratory or Designee is responsible for auditing the Personnel Evaluation Roster at least annually for nonwaived testing personnel and personnel fulfilling supervisor roles.

### The Laboratory is responsible for determining job qualifications, interviewing candidates, hiring candidates.

## Personnel

### The Laboratory employs an adequate number of qualified individuals

### Qualifications and Job Descriptions

Job descriptions define appropriate qualifications (defined as education, training, and experience) for each position and are kept current. Personnel performing critical tasks are qualified based on appropriate education, training, and experience.

All persons hired to perform high-complexity testing at GENETWORx must possess, at minimum, either:

1. A Bachelor’s Degree in medical technology, clinical laboratory, chemical, physical or biological science.
2. Associate degree in a laboratory science (chemical or biological science) or medical laboratory technology from an accredited institution, or equivalent laboratory training and experience meeting the requirements defined in the CLIA regulation 42CFR493.1489 (see NOTE 2).
3. For high complexity testing, equivalent laboratory training and experience includes the following:
   1. 60 semester hours or equivalent from an accredited institution that, at a minimum, includes either 24 semester hours of medical laboratory technology courses, OR 24 semester hours of science courses that include six semester hours of chemistry, six semester hours of biology, and 12 semester hours of chemistry, biology or medical laboratory technology in any combination; AND
   2. Laboratory training including either completion of a clinical laboratory training program approved or accredited by the ABHES, NAACLS, or other organization approved by HHS (note that this training may be included in the 60 semester hours listed above), OR at least three months documented laboratory training in each specialty in which the individual performs high complexity testing.

### Training

The Laboratory maintains a process for identifying training needs, and a process for training personnel who perform activities affecting quality.

### Competence

The Laboratory maintains processes for evaluating competence after initial training and for evaluating continued competence at specified intervals.

### Personnel Records

The Laboratory maintains personnel records for each employee. Records are retained per the Document Retention Policy (Refer to policy QP 600)

# Laboratory Personnel Record Maintenance

## Responsibility

Personnel files are maintained on all Laboratory personnel by the Laboratory.

## Records to be Maintained by Supervisor Sections

The supervisor of each section maintains all files for employees in that section and includes the following:

### Mandatory training and education records such as annual compliance training

### Fire and Safety Training (may also be maintained by Human resources)

### Confidentiality Statement (may also be maintained by Human resources)

### Initial Departmental Orientation documentation-including safety training

### Records and certifications of continuing education related to the section

### Records of radiation exposure where applicable

### Incident and/or accident reports

### Disciplinary records

### Competency assessments-initial, during first year, and annually thereafter

### Remedial or corrective action because of unsatisfactory performance or competency assessment

## Personnel files maintained by the Human Resources and Employee Health Department

### Summary of training, experience, and credentials before hiring

### Job description (description of duties)

### References from previous employers

### Administrative orientation records

### Records of advancements

### Health records (including Color blind test, inoculations)

### Introductory and annual performance reviews

### Disciplinary actions

# Continuing Education

## Policy:

It is the policy of this Laboratory to provide and maintain records of continuing education of each employee. Hardcopies of sign in sheets are maintained in the section where the employee is assigned to work.

## Policy:

### The purpose of this procedure is to ensure that continuing education is provided and documentation is maintained on each employee which can be located as needed.

### Laboratory personnel are encouraged to enhance and supplement their knowledge and skills as often as reasonably possible. These records will be stored in the Human Resources department. It is the responsibility of the employee to submit these records to management for archival.

### Continued education can be accomplished through the following:

#### Regional, state, and national conferences

#### Teleconference

#### In-service

#### Peer review and instruction

#### Articles

#### Laboratory Lectures

#### Other educational materials

### GENETWORx also will encourage each employee to prepare for certification process in the Laboratory Discipline in which that employee has interest.

### Accreditation for testing samples received from the state of New York requires a minimum of 13 hours of continuing education per year.

# Charge Tech Policy

## Policy:

### In the absence of an on-site Laboratory supervisor or lead technologist, a charge tech will be assigned to ensure the smooth operation of the Laboratory. The charge tech will be rotated amongst qualified staff to facilitate personnel management and workflow.

### The duties of the charge tech include, but are not limited to, the following items:

#### Provide for adequate coverage of the Laboratory in the event of an unscheduled absence. This may include assessing staffing levels, finding coverage and assigning personnel.

#### Act as the Laboratory Unit Leader in the event of a disaster until a supervisor is present. Assist in the resolution of any problems and/or inquiries.

#### Communicate any problems or issues to the appropriate section supervisor or lead tech. enlist the assistance of the Lab Coordinator if necessary.

#### Monitor the workflow throughout the Laboratory to provide for the timely reporting of results and that critical area results are reported within established turn around times.

#### Coordinate breaks/lunches/dinners if necessary so that everyone has an opportunity for a break and the GENETWORx policy is followed regarding length of breaks.

### Qualified staff includes any Medical Technologist, Medical Laboratory Technician or Scientist that has successfully passed the training probationary period, work two months after passing probation and is not currently under a disciplinary action in the past six months. The Lab Leadership Team will make the final determination on who may assume the role of charge tech.

# Part Time Personnel Policy

## Policy:

### Laboratory staffing is determined annually through the budget process that includes volumes and projected trends by the Laboratory Manager. The Laboratory Manager sets criteria for employment, deployment and assignment of Laboratory staff members.

### Part Time (CPT) employees provide the Laboratory sections with flexible staffing to ensure the efficient operation of the department as well as meet the staffing needs of the sections due to varying test volumes, patient census or staff vacancies (i.e. openings, FMLA, CLB, etc.). Part time staff must meet all criteria regarding eligibility for employment as well as regulatory (CLIA) guidelines for working in the Laboratory.Part time staff must also meet the following criteria:

#### One year of relevant laboratory experience, preferred.

#### Attend employee orientation.

#### Successful completion of department-specific training.

#### Successful completion of annual compliance training.

#### Successful completion of annual fire and safety training.

### Part time employees are required to work the following schedule:

#### One weekend in a 4-week/28-day period. Weekend shifts are from 800 hours to 1700 hours Saturday.

#### One summer holiday (Memorial Day, July 4th, Labor Day) a year; and

#### One winter holiday (Thanksgiving, Christmas, New Years Day) a year; and

#### One additional shift in a two month block (Jan-Feb, Mar-Apr, May-June, Jul-Aug, Sep-Oct, Nov-Dec)

### The supervisor or lead tech has the authority to “call-off” the CPT staff if the section does not need to use the CPT employee.

### All GENETWORx Policies and Procedures apply to the part time staff except as specified under this policy. Part time staffs are not guaranteed hours. The part time policy will be subject to periodic evaluation and revisions at the discretion of the Laboratory Leadership Team.

# Privacy Policy

## Objective:

### To provide practices protecting the confidentiality, privacy, and security of all Protected Health Information in compliance with patient expectations, regulations, and community standards; including but not limited to the Confidentiality of Medical Information Act and Health Insurance Portability and Accountability Act (HIPAA.)

## Responsibility:

### The Medical Records Supervisor is responsible for the maintenance of this protocol. All GENETWORxStaff have a responsibility to assist in the maintenance and compliance of this protocol.

## Protocol:

### Medical Records Staff will never under any circumstances release Medical Record Information without a signed Authorization for Use and/or Disclosure of Protected Health Information Form.

### Patients may request a copy of their Medical Health Information record by completing and signing an ***Authorization for Use and/or Disclosure of Protected Health Information Form (Quality Manual Attachment 3).*** All *GENETWORx* staff will make sure that the patient provides the following when assisting a patient with any *Authorization for Use and/or Disclosure of Protected Health Information Form.*

#### Verifies the patient’s identity by Driver’s License, passport or similar picture identification. A copy of the patient identification will be attached to the signed authorization.

#### Have the patient sign Authorization for Use and/or Disclosure of Protected Health Information Form, before releasing information.

#### The Authorization for Use and/or Disclosure of Protected Health Information Form must be signed by a witness.

#### Medical Records Staff will process all completed requests within 5-10 business days of the dated Authorization for Use and/or Disclosure of Protected Health Information Form.

### The Authorization for Use and/or Disclosure of Protected Health Information Form must consist of the following:

#### Handwritten by the patient or patient designee.

#### The form must be dated.

#### Per the Insurance Information & Privacy Protection Act - the length of time the authorization shall remain valid, will be no longer than 30 days from the date the authorization is signed, if the request involved life, health or disability insurance.

### The Patient Medical Authorization for Use and/or Disclosure of Protected Health Information Form may be signed and dated by any one of the following:

#### A patient may designate a representative to access their Medical Record. The representative must have written documentation/authorization, show the required identification and complete the required Authorization for Use and/or Disclosure of Protected Health Information Form.

#### A minor (under 18 years of age) needs the consent of his/her parent or legal guardian unless the minor has a right to his or her own treatment consent

#### Proof of executor of estate is required if a relative/representative of a deceased patient is requesting a medical record copy along with the required identification and completion of the Authorization for Use and/or Disclosure of Protected Health Information Form.

### Patient Medical Records may be transmitted to a requesting physician or facility via Facsimile Machine making sure that the transmission is confidentially directed and received after receipt of signed, dated physician/facility release of information form**.**

### Medical Records Staff will never under any circumstances release Medical Record Information via telephone**.**

## Information that may or may not be released without authorization

The following issues may be discussed with outside entities without authorization:

### The laboratory services that are performed by GENETWORx

### The specimen type and preparation required to perform laboratory services

### The methods of shipment of a specimen type to the laboratory

### The marketed turnaround time of laboratory services

## The following issues are not to be discussed and are subject to disciplinary actions:

### Patient specific information to include name, turnaround time, or confirmation that a specific specimen has been received

### Patient diagnoses are not to be released by laboratory personnel.

## Personnel review of PHI

### Members of the medical staff, trainees, laboratory technicians, quality control personnel, etc. can review medical records to determine any quality assurance or quality control issues.

### All of the employees of GENETWORx are trained in HIPAA act and understand the importance of confidentiality. PHI may be disclosed as required by law, or in a variety of circumstances authorized by federal or state law (for example, state tumor registries).

### All employees of GENETWORx must complete the HIPAA Confidentiality Agreement (Quality manual Attachment 4)

## Receipt and handling of Private Health Information from other entities

### Any PHI received from other entities must be received by secure means (secure fax). Outside entities that handle PHI from GENETWORx must acknowledge GENETWORx’ privacy policy.

## Sanctions:

### Any release or disclosure of patient specific Private Health Information by laboratory personnel is subject to disciplinary actions.

### Any release or disclosure of patient specific Private Health Information to an unauthorized individual must be reported to the Laboratory Manager of GENETWORx.

### Intentional disclosure or release of patient specific Private Health Information is cause for immediate dismissal.

## Audits:

At least annually, the compliance with HIPAA must be audited and this audit documented. Reference Quality Manual Attachment 5. HIPAA audit form.

## References:

### 45 C. F. R. §§160 - 164.524(HIPAA)

### 10 NYCRR § 58-1.10(g)

# Competency Assessment Policy

## Policy

It is GENETWORx’ policy that all laboratory personnel will undergo competency assessment upon initial employment, 6 months from initial competency, and annually thereafter.

|  |  |  |
| --- | --- | --- |
| Who is Responsible | What Happens | Documents |
| Supervisor or designee | Establishes acceptable performance standards before assessment exercises are performed and consistently applies such performance standards to staff who perform similar tasks.  1. Assesses competence: 2. After training 3. Semiannually within the first year 4. At least annually thereafter 5. Uses all of the following means to determine competence: 6. *Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing* 7. *Monitoring the recording and reporting of test results, including, as applicable, reporting critical results* 8. *Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records* 9. *Direct observation of performance of instrument maintenance and function checks* 10. *Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and* 11. *Evaluation of problem-solving skills* | Competence assessment tools:   * Worksheets, etc * QC records * Maintenance results * Direct observation checklists * Proficiency survey results * Written cases or evaluations * Compliments or complaints * Proficiency surveys |
| Staff | Successfully completes assessments at conclusion of trainingAccepts and performs assigned assessment challengesRecords all results and signs/dates assessments | Assessment forms, where applicable |
| Supervisor or designee | 1. Documents interpretations of assessments  2. Initiates remedial measures when training needs are identified  3. Documents outcomes | Assessment forms, where applicable |
| Staff | Accepts and performs additional assignments when training needs identified. | Assessment forms, where applicable |

## References:

### Food and Drug Administration, Department of Health and Human Services, Title 42, Code of Federal Regulations, Parts 493 to end. Washington, DC

### Transfusion Service Manual of Standard Operating Procedures, Training Guides, and Competence Assessment Tools. AABB, 1996. Bethesda, MD.

# Personnel New Hire Policy

|  |  |  |
| --- | --- | --- |
| Who is Responsible | What Happens | Documents |
| Lab Leadership | * Determines minimum educational requirements for each job. * Writes job description | Job Descriptions |
| Human Resources  Lab Leadership | * Defines application process | HR policy manual |
| Lab Leadership | * Reviews applications * Interviews appropriate applicants * Hires or rejects applicants | Job application  Resume  Interview Documentation Form |
| Human Resources | * Contacts selected applicant with salary offer * Explains benefit package * Arranges parking * Provides ID badge |  |
| Lab Leadership  Information Systems | * Request computer password from IS | Password request templates in Lab Shared |
| Department Supervisor or designee | Orient new employee to:   * lab safety * compliance * time and attendance system * physical layout of the lab * use of locker * computer – OA, password, confidentiality, downtime | * Lab Orientation Checklists * Laboratory Personnel Safety Data * New Employee Orientation Checklist * Safety Orientation Checklist |
| Human Resources | * Initial orientation – first Monday of the month | * GENETWORx Personnel Handbook * Initial Hire form |

# Personnel Training Process

## The following process is implemented for training of new employees:

|  |  |  |
| --- | --- | --- |
| Who is Responsible | What Happens | Documents |
| Lab Management and Human Resources | Maintains job descriptions for all staff | Job Descriptions |
| Human Resources | Conveys organizational knowledge | Employee Handbook |
| Lab Management | Conveys Lab departmental knowledge:  Lab physical layout  Storage of personal items  Breaks and meals  Safety  Supply processes | 1. Lab orientation checklist  2. Departmental Safety  Manual  3. Material Safety Data  Access Procedure  (MSDS)  4. Right-to-Know Laws |
| Lab Management | Maintains training documents that describe required training for all staff | Training checklists |
| Lab Management | Determines trainer competence |  |
| Trainer | Provides job-specific training | Training checklists |
| Employee | Completes required training and gives completed documents to trainer | Training checklists |
| Supervisor  Trainer | Evaluates completed training documents  Determines employee’s initial competence  Approves employee for job task performance | Completed checklists  Completed competence assessment tools if any |

**Revision History**

|  |  |  |  |
| --- | --- | --- | --- |
| Revision Number | Reason for Revision | Author | Effective Date |
| 0 | Original SOP | Bill Miller | Upon Signature |
| 1 | Reformat Quality System, Add CEO signature Line, update personnel requirements per CAP General Checklist, Update elements to be reviewed for competency. | Sarah Jacobs-Helber | Upon Laboratory Director Signature |

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| --- | --- | --- |
| **Review & Approval History** | | |
| **Printed Name** | **Signature** | **Date** |
| Sarah Jacobs-Helber, PhD HCLD(ABB), Laboratory Director |  |  |
| William Miller, HTL, MBA Chief Executive Officer |  |  |

**Reviewed by:**

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