|  |
| --- |
| ***Insert Laboratory Specific Name Here*** |
| **Bioinformatics Personnel Training Standard Operating Procedure** |

1. **Purpose**

This document describes standard operating procedures to be followed by public health laboratory personnel in developing and implementing training courses for the purpose of training personnel to acquire and demonstrate the skills and knowledge necessary to perform the bioinformatics analysis. Bioinformatic analysis includes the use of informatics tools and methods for analysis of Next Generation Sequencing data. Bioinformatics personnel training employs the Tell, Show, Do, Apply learning strategies. These four learning strategies have been shown to increase learning and engagement. *Tell* provides the trainee with key information related to their learning. *Show* provides the trainee an opportunity to observe the trainer demonstrate what is being taught. *Do* provides the trainee with an opportunity to do what they have been taught. *Apply* gives the trainee an opportunity to independently apply the information they have learned.

1. **Scope**

This document applies to all bioinformatics analysts and bioinformatics supervisors that oversee these operations. Training includes building a base of knowledge, observing the trainer perform the procedures, performing procedures under direct trainer supervision, and a training assessment in the form of independently executing the procedures.

1. **Related Documents**

|  |  |
| --- | --- |
| **Title**  | **Document Control Number**  |
| *\*List applicable Bioinformatics Training Forms\** |  |

1. **Responsibilities**

|  |  |
| --- | --- |
| **Position**  | **Responsibility**  |
| Trainee  | • Complete all necessary training requirements  |
| Bioinformatics Team Lead | * Determine the training needs for the laboratory staff
* Ensure all staff are trained and evaluated according to this procedure
* Create training plans, review training materials, and assign trainers as needed
* Develop training materials
* Document training activities using the Training Form
 |
| Trainer  | * Provide and document training per the SOP, using the Training Form
* Possess competence in the training topic. Trainers may be vendors or laboratory personnel (either FTE or contractor), provided they have experience in the training topic.
 |

1. **Procedure**
	1. **TELL: Base Knowledge (Section I)**

The trainee will be provided with a list of resources for required reading and/or watching. Resources may include any applicable laboratory developed risk assessment/mitigation documents, SOPs, publications, instrument manuals, and any other applicable information.

1. List the required resources for review in Section I of the Training Form*.*

Note: If the trainee will perform only a portion(s) of the overall test method, they are only required to read the documents relevant to the portion(s) they will perform.

1. The trainee will build a basic understanding of the testing they are to perform by completing the required reading/watching listed in Section I of the Training Form.
2. The trainee will become acquainted with the primary user responsibility to ensure that preventative maintenance is scheduled and executed for all equipment involved in testing.
	1. **SHOW: Observation (Section II)**

 The trainer will perform all steps within the SOP while the trainee observes.

1. The trainer will verbally walk the trainee through the entire process from beginning to end using the operational SOP as a training guide.
2. This review will cover all aspects of the total test process for which the trainee will be responsible to perform.
3. The trainer will discuss key steps and troubleshooting topics listed in Section II of the Training Form.
4. The trainee will observe proper user performed preventive maintenance.
	1. **DO: Performance under Supervision (Section III)**

The trainee will perform all steps within the total test process that they will be responsible to perform under direct and full observation of the trainer. The trainee will perform any user performed preventive maintenance required.

1. The trainer will document in Section III of the form the success/failure of the trainee to meet the performance criteria.

i. If the trainee fails to meet the criteria, the trainer will assess the cause of the failure and will provide additional training until the trainee is able to successfully meet the performance criteria. Remedial training may be documented in the notes section of the Training Form.

1. The trainer will assess the trainee’s ability to properly maintain the environment according to established maintenance procedures.
	1. **APPLY: Post Training Assessment (Section IV)**

Once the trainee successfully performs the process under the observation of the trainer, the trainee will perform the post training assessment.

1. The trainer will review the trainee’s results and compare them to the expected results to assess the trainee’s performance.
2. The trainer will record the success/failure of the trainee to meet the performance criteria in Section IV of the Training Form.

i. If the trainee fails to meet the criteria, the trainer will assess the cause of the failure and will provide additional training until the trainee is able to successfully meet the performance criteria. Remedial training may be documented in the notes section of the Training Form. Steps 5.1 through 5.4 may be repeated as necessary to ensure successful completion of training.

* 1. **Trainee Attestation (Section V)**

The trainee will complete Section V of the Training Form.

* 1. **Review and Signatures (Section VI)**

The trainer will ensure completion of Section VI of the Training Form.

1. Both the trainee and trainer will review and sign the Training Form.
2. For CLIA test systems only: If the trainer is neither a General Supervisor nor a Technical Supervisor, an additional review and signature is required by either a CLIA General Supervisor or a CLIA Technical Supervisor.