# Standard Operating Procedures for Mental Health Assessment

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**Table of contents**

[1. PURPOSE 3](#_Toc166237661)

[2. SCOPE 3](#_Toc166237662)

[3. RESPONSIBLE FUNCTIONS 3](#_Toc166237663)

[4. DEFINITIONS and ABBREVIATIONS 3](#_Toc166237664)

[5. PROCEDURE: 3](#_Toc166237665)

[5.1 Materials needed for Mental Health Assessment 3](#_Toc166237666)

[5.2 Preparation 3](#_Toc166237667)

[5.3 Test environment 3](#_Toc166237668)

[5.4 Introduction 3](#_Toc166237669)

[5.5 Patient Self-administration of PHQ-9 3](#_Toc166237670)

[5.6 Performing the PHQ-9 3](#_Toc166237671)

[5.7 Patient Self-administration of GAD-7 4](#_Toc166237672)

[5.8 Performing the GAD-7 4](#_Toc166237673)

[6. REFERENCES 5](#_Toc166237674)

[7. APPENDIX 5](#_Toc166237675)

# Standard Operating Procedures for: Mental Health Assessment

## PURPOSE

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| This standard operating procedure (SOP) describes the procedures for performing the assessment of mental health of the study participants using standardized and validated instruments for the detection of depression and anxiety disorders.  The Patient Health Questionnaire (PHQ-9) is a multipurpose instrument for screening, diagnosing, monitoring, and measuring the severity of depression. The Generalized Anxiety Disorder Assessment (GAD-7) measures the severity of anxiety symptoms. |

## SCOPE

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| This SOP applies to trained healthcare workers assessing mental health in participants of the endTB observational study and clinical trial. |

## RESPONSIBLE FUNCTIONS

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| **Function** | **Activities** |
| **Site Principal Investigator (site-PI)** | * Supports the delegated site personnel in ensuring that the mental health assessment is performed according to the study protocol |
| **Delegated site personnel** | * Prepares environment and informs the patient * Administrates PHQ-9 and GAD-7 tests * Records the total scores of PHQ-9 and GAD-7 tests |

## DEFINITIONS and ABBREVIATIONS

**Patient Health Questionnaire (PHQ-9):** The PHQ-9 is a multipurpose instrument for screening, diagnosing, monitoring, and measuring the severity of depression. The PHQ-9 can be administered repeatedly, which can reflect improvement or worsening of depression in response to treatment.

**Generalized Anxiety Disorder Assessment (GAD-7):** The GAD-7 is an instrument for measuring the severity of anxiety symptoms. The GAD-7 consists of 7 items, each defined by a series of symptoms, evaluating the presence of generalized anxiety disorder.

## PROCEDURE:

### Materials needed for Mental Health Assessment

* Patient Health Questionnaire (PHQ-9) scoring sheet (Appendix 1)
* Generalized Anxiety Disorder Assessment (GAD-7) scoring sheet (Appendix 2)

### Preparation

**Delegated site personnel** should be trained on administering the PHQ-9 and HAM-A tests.

### Test environment

The ideal test room is quiet and free of distractions. It is important to make the patient feel at ease and assure the complete confidentiality of the discussion.

### Introduction

**Delegated site personnel** prepares the execution of the test by following this procedure:

* Introduce one’s self and verify the subject’s Full name and date of birth.
* Describe the scale and its purpose in a way that is relevant for the specific patient and for the specific assessment.
* Ask the patient in a non-confrontational way if s/he would prefer to complete the questionnaire independently or if s/he would prefer to have the questions asked by the study staff.

### Patient Self-administration of PHQ-9

If the patient elects to self-administer the PHQ-9 questionnaire, **delegated site personnel** should instruct the patient to reach item and circle the one reply that comes closest to how the patient has been feeling over the past two weeks.

### Performing the PHQ-9

If the patients elects to have the questionnaire administered by the delegated site personnel, the **delegated site personnel must** perform the test according to the following procedure:

* Review the list of the 9 questions of the PHQ-9 questionnaire in Appendix 1
* Ask the patient each question exactly as written in the questionnaire. The two week time interval should be repeated for each question. The answer choices should also be stated exactly as written in the questionnaire
  + Example for question 1: “Over the past 2 weeks, how often have you been bothered by little interest or pleasure in doing things? The answer choices are not at all, several days, more than half the days, or nearly every day. Please choose one.”
  + Example for question 2: "Over the past 2 weeks, how often have you being bothered by feeling down, depressed or hopeless? The answer choices are not at all, several days, more than half the days, or nearly every day. Please choose one.”
  + Example for question 3: “Over the past 2 weeks, how often have you been bothered by Trouble falling asleep, staying asleep, or sleeping too much? The answer choices are not at all, several days, more than half the days, or nearly every day. Please choose one.”
* For every question, check the column according to the patient’s response (not at all, several days, more than half the days, nearly every day)
* After having asked all questions, assign the points for every line according to the checked column (not at all = 0, several days = 1, more than half the days = 2, nearly every day = 3)
* Add together all line scores to get a total score
* Refer to the following Grading Box to grade the total score:
  + 1-9: Grade 1
  + 10-14: Grade 2
  + 15-19: Grade 3
  + 20-27: Grade 4
* **Delegated site personnel** record the total score and grade of the test

### Patient Self-administration of GAD-7

If the patient elects to self-administer the GAD-7 questionnaire, **delegated site personnel** should instruct the patient to reach item and circle the one reply that comes closest to how the patient has been feeling over the past two weeks

### Performing the GAD-7

**If the patient elects to have the questionnaire administered by delegated site personnel, the delegated site personnel must** perform the test according to the following procedure:

* Review the list of the 7 items of the GAD-7 questionnaire in Appendix 2
* Ask the patient each question exactly as written in the questionnaire. The two week time interval should be repeated for each question. The answer choices should also be stated exactly as written in the questionnaire
  + Example for question 1: “Over the past 2 weeks, how often have you been bothered by feeling anxious, nervous or on edge? The answer choices are not at all, several days, more than half the days, or nearly every day. Please choose one.
  + Example for question 2: “Over the past 2 weeks, how often have you been bothered by not being able to stop or control worrying? The answer choices are not at all, several days, more than half the days, or nearly every day. Please choose one.”
  + Example for question 3: “Over the past 2 weeks, how often have you been bothered by worrying too much about different things? The answer choices are not at all, several days, more than half the days, or nearly every day. Please choose one.”
* For every question, check the column according to the patient’s response (not at all, several days, more than half the days, nearly every day).
* After having asked all questions, assign the points for every line according to the checked column (not at all = 0, several days = 1, more than half the days = 2, nearly every day = 3)
* Add together all line scores to get a total score
* Refer to the following Grading Box to grade the total score:
  + 1-4: Grade 1
  + 5-9: Grade 2
  + 10-14: Grade 3
  + 15-21: Grade 4
* **Delegated site personnel** record the total score and grade of the test

## REFERENCES

* Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med 2001; 16(9):606-13.
* Spitzer RL, Kroenke K, Williams JBW, Löwe B. A brief measure for assessing generalizedanxiety disorder: the GAD-7. Arch Intern Med 2006;166:1092-1097.

## APPENDIX

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| **Appendices & Forms for completion** | |
| **Number** | **Title** |
| 1 | Patient Health Questionnaire (PHQ-9) scoring sheet |
| 2 | Generalized Anxiety Disorder Assessment (GAD-7) scoring sheet |