**Study Number & Rev.:** IRB Protocol CL-006

**Identifiers:** NCT03469128

**Study Title:** Cognitive Processing Therapy Versus Sertraline for the Treatment of Comorbid Substance Use Disorder and Post-Traumatic Stress Disorder in Egyptian patients

**Study Design:** Randomized clinical trial

**Sponsor Name:** The British University in Egypt

**Sponsor Address:** El-Sherouk City, Cairo, Egypt

**Data Analysis:** 01-01-2016

**Expected Completion Date:** December 2019

**Principal Investigator:** Dr. Amani Elbarazi, Clinical Practice Department, Faculty of Pharmacy, The British University in Egypt, P.O. Box 43, El-Sherouk City, Cairo 11837, Egypt

**STATEMENT OF CONFIDENTIALITY**



**Protocol signature page**

The undersigned has read and understood the trial protocol detailed above and agrees to conduct the trial in compliance with the protocol.

| Dr. Amani Elbarazi | Amani | BUE3570 | 01-01-2016 |
|---|---|---|---|
| **Principal Investigator** (Please print name) | **Signature** | **Site name or ID number** | **Date** |

# Consent Form

**Project: Cognitive Processing Therapy Versus Sertraline for the Treatment of Comorbid Substance Use Disorder and Post-Traumatic Stress Disorder in Egyptian patients**

**Principal investigator:** Amani Elbarazi

1- I confirm that I have read and understood the information sheet for the above study and had the opportunity to contact the researchers to ask questions. ☐

2- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my treatment being affected. ☐

3- In the case of withdrawal I understand that any information collected up to that point can still be used by the researchers ☐

4- I agree to take part in study parts 1 & 2 and I am aware that this involves answering a set of assessments and filling out questionnaires and assessments on paper copies. ☐

5- I agree to supply the researcher with my contact details and those of my GP/ Consultant. These details will be supplied below. ☐

Name of Participant _____ Date _____ Signature _____

Researcher Dr. Amani Elbarazi Date _____ Signature _____

Please supply your GP/Consultant details below
Name: ……

Address: ……

……

MANY THANKS FOR AGREEING TO TAKE PART IN THIS STUDY.