**Research projects that involve patients or staff of University Behavioral Health Care must be approved by the Chief Financial Officer and the President and CEO, UBHC, before submission to the Institutional Review Board.**

**TITLE OF PROJECT: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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**DATES OF STUDY: FROM \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_TO\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**PRINCIPAL INVESTIGATOR: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**CO-INVESTIGATOR(S): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**IS THIS PROJECT A CLINICAL TRIAL? ❒ YES ❒ NO**

**WILL EXTERNAL (i.e., NON-UBHC) FUNDING SUPPORT THIS PROJECT? ❒ YES ❒ NO**

**WILL PHI DATA BE RELEASED AS IN AN EPIDEMIOLOGICAL STUDY? ❒ YES ❒ NO**

**If yes, this needs to be reviewed and authorized by the Director of Clinical Records before information is released by Information Services.**

**Provide a brief plain language summary of the project that addresses the following issues:**

1. **Client recruitment and scheduling at UBHC sites. Client recruitment and scheduling of appointments are to be arranged through the local UBHC unit so that treatment services are not interrupted and potential compliance issues addressed. Specify the administrative staff with whom the project has been reviewed at the local unit level. Specify each UBHC site and budgeted UBHC indirects.**
2. **Interventions to be provided (both therapeutic and/or medication).** 
   1. **If therapeutic, specify the intervention, the target group, the dose, the schedule and who will be providing the intervention (privileging will be required).**
   2. **If medication, specify what medication, the target group, cost (if medication is provided free and then continued after the study is complete and the plan to address this), the dose. Also specify whether any medication storage will be required through the pharmacy.**
3. **The use of any incentives. Specify what kinds and discuss how any issues regarding their use will be addressed.**
4. **Will UBHC staff to be involved in the study? Specify which staff, their role in the study and the nature of the involvement.**
5. **Will UBHC facilities be required in this study? ❒ YES ❒ NO**

**Specify any type of testing that will be required (such as laboratory or EKG, or other).**

**IF YES, SPECIFY THE FOLLOWING:**

* 1. **Anticipated number of participants in study protocol\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
  2. **(Please include the schedule of visits from the research protocol as well as the laboratory protocol if available)**
  3. **Length of study\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
  4. **Phlebotomy with samples processed and sent to an outside lab ❒ YES ❒ NO**
  5. **Phlebotomy and testing done at UBHC ❒ YES ❒ NO**
  6. **Waived Testing Required ❒ YES ❒ NO**
  7. **EKG Required ❒ YES ❒ NO**

**THIS PROJECT HAS BEEN DISCUSSED WITH RESPONSIBLE UBHC CLINICAL LEADERSHIP**

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**Signature, Vice President or Designee Date**

**2.** **Upon completion of the research project, the Principal Investigator shall debrief participants in order to remove any confusion, misinformation, stress, physical discomfort, or other harmful consequences that may have arisen as a result of study participation.**

**3. Upon completion of the research project, the Principal Investigator, whether a member of UBHC staff or an outside researcher, shall be responsible for communicating the purpose, nature, outcome, and possible practical or theoretical implications of the research to the staff of the program involved in the project.**

**4. A brief summary of all research projects shall be submitted to the President and CEO’s Office and the Quality Improvement and Patient Safety Committee, UBHC, and shall be maintained by the facility.**

**5. The Principal Investigator also attests that s/he will ensure compliance with the above and will also enter any required data into the UBHC research database on a monthly basis.**

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**Principal Investigator Date**

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**Director of Research, University Behavioral Health Care Date**

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**\_\_\_\_\_ PERMISSION GRANTED \_\_\_\_\_PERMISSION DENIED**

**\_\_\_\_\_ PERMISSION GRANTED with the following stipulations: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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**Carl O’Brien Date**

**Chief Financial Officer, University Behavioral Health Care**

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**Dr. Frank Ghinassi Date**

**President and CEO, University Behavioral Health Care**