CHAMBERLAIN UNIVERSITY

IRB Pre-Screening Review Form

Step 1: Determination of Whether the Project is "Research" as Defined by the IRB

1. Is your project intended to generate new knowledge that will be or is desired to be applied beyond the setting(s) at which the project is conducted?

   ◯ Yes ◯ No

2. Is your project designed to expand theory or inform policy that goes beyond the project setting(s)?

   ◯ Yes ◯ No

3. Will your project implement an intervention that has not been published as being used/ tested in your population of interest?

   ◯ Yes ◯ No

4. Will your project implement an intervention using a protocol that deviates *substantively* from how the protocol has been used previously?

   ◯ Yes ◯ No

5. Will the project replicate or extend a previous research study?

   ◯ Yes ◯ No

Step 2: Determination of Whether the Project includes Human Subjects

6. Will your project involve collecting, using, studying, analyzing, or generating data, information, or biospecimens by interacting with or intervening with living humans?

   ◯ Yes ◯ No

7. Will your project involve collecting, generating, using, studying, or analyzing identifiable* private**information, identifiable biospecimens, and/or protected health information?

*Data, information, or biospecimens for which the identity of the subject is or may be readily ascertained (e.g. through codes or other types of alternative identifiers) by the investigator or associated with the information or biospecimens.

**Data, Information, or biospecimens that occurs or are collected in a context in which the individual can reasonably expect that no observation or recording is taking place or will not be made public, and for which the identity of the subject is or may be readily ascertained by the investigator or associated with the information or biospecimens.

   ◯ Yes ◯ No

If you answered "Yes" to any of questions #1 through #5 in Step 1 <u>and</u> any question in Step 2, then your project is congruent with Chamberlain's definition of human subjects research and you must submit the full IRB application packet for IRB review and approval.

Step 3: Additional Information

8. Does the practice setting require that this project be reviewed by the setting's IRB or other review committee?

   ◯ Yes ◯ No

9. Does the project involve interacting directly with or having a direct impact on any of the following populations? (Identification of a vulnerable population does not always require the project to go to the IRB for a complete review).

   ◯ Yes ◯ No Persons below the age of 18 years

   ◯ Yes ◯ No Persons with cognitive impairment

   ◯ Yes ◯ No Prisoners

   ◯ Yes ◯ No Pregnant women, human fetuses, or neonates

   ◯ Yes ◯ No Persons institutionalized

10. Will Chamberlain students, faculty, or staff be the subjects of the proposed project?

◯ Yes ◯ No

What is your project's question?

11. Enter your practice question in the space provided below. The practice question should follow the PICOT format and include a specific population, the practicum site name (if permissible from the practicum site), the evidence-based intervention, the comparison, measurable outcome and timeline for the project. If any element from the PICOT format is missing in your practice question - the IRB prescreening form will be returned for correction.

Student Name (Printed)_____

Student Signature _____Date_____

I have reviewed the student's practice question and attest to the accuracy of the responses to the prescreening criteria questions. All elements of the practice question are present.

Faculty Signature_____Title_____Date_____

Faculty Signature_____Title_____Date_____

Faculty Signature_____Title_____Date_____

Faculty Signature_____Title_____Date_____