 **Institutional Review Board Application for Review of Proposed Study**

**Chamberlain University Institutional Review Board**

**500 W. Monroe, Suite 1300 Chicago, IL 60661**

**Email:** **irb@chamberlain.edu**

**IORG0008174 / IRB00011037 FWA00021986**

**Instructions: Please complete all items on this form. If any item is non-applicable, then state “non-applicable”. Incomplete applications will not be returned to the investigator. The content of this application as well as all supporting documents will be kept confidential within the limits of the law. *All applicants must submit this completed application and await the disposition of the application outcome before proceeding with the proposed study. Do not edit or revise the application form.***

1. **STUDY TITLE:**
2. **PRINCIPAL INVESTIGATOR:**

 Name:       Title:

 Affiliated Program, Campus, or Department:

 Mailing Address:

 This address is:  **[ ]** Home[ ]  Work

 Work Phone:       Home Phone:       E-mail Address:

1. **CO-INVESTIGATORS:**

Name:       Email Address:

 Institutional Affiliation:

Name:       Email Address:

 Institutional Affiliation:

Name:       Email Address

 Institutional Affiliation:

 *(Add more as needed)*

1. **SUPERVISING FACULTY (Complete this section if the proposed study will be conducted in partial completion of the investigator’s academic program):**

Name:       Title:      Affiliated Program:

Mailing Address:

This address is:  **[ ]** Home[ ]  Work

Work Phone:       Home Phone:       E-mail Address:

**V. PROJECTED DATES OF RESEARCH** (for Subject Recruitment, Data Collection, Data Analyses):

Start Date: ***UPON IRB APPROVAL*** End Date:

**VI. LOCAL LAWS**

The investigator must ensure that components of the proposed study comply with local state laws relating to human subject protections. If applicable, the investigator must list local state laws that apply to the study and explain how they have been incorporated for compliance. If no state laws apply to the study, please indicate this.

**VII. EXISTING DATA**

Will this study involve the use of existing data, documents, records, and pathological specimens?

**No** **[ ]  Yes** **[ ]  If yes, include a** **letter of authorization to access any data that are not already available to the investigator as part of their usual role or are not already publicly available**.

**VIII. MULTI-INSTITUTION AND MULTI-SITE STUDIES**

Will multiple institutions participate in this study? Yes [ ]  No [ ]

 If “Yes”, which institutions will participate?

 Will multiple sites/ locations participate in this study? Yes [ ]  No [ ]

 If “Yes”, which sites/ locations will participate?

**IX. STUDY DESCRIPTION**

1. **STUDY ABSTRACT / OVERVIEW.** In **200 words or less**, describe in **lay language** the nature, purpose, methods, risks, and risk management procedures of the proposed study. ***PLEASE BE CONCISE.***

1. **STUDY PURPOSE OR AIMS**. In **lay language**, briefly describe the overall purpose or aims of the study.

## **STUDY HYPOTHESES, QUESTIONS, OR OUTCOMES**

1. List the study hypotheses, research questions, or study outcomes that address the study’s purpose/ aims.

2. Briefly describe how each of the hypotheses will be tested, questions answered, and/or outcomes measured.

 3. Are you using a questionnaire, survey instrument, or interview as part of your procedure?

 Yes [ ]  No [ ]

 *If yes, submit a copy of the questionnaire(s), survey(s), or interview questions.*

## **D. SUBJECTS: Fill in as applicable if you will be recruiting human subjects**

**1. Subjects to be Recruited** (check all that apply)

 [ ]  Adults (18-65 years)

 [ ]  Older Adults (>65 years)

 [ ]  Children and Minors (< 18 years)

 [ ]  Individuals with Impaired Decision-Making Capacity

 [ ]  Prisoners [ ]  Ethnic/ Racial/ Religious or Other Minoritized Groups:

 Please specify:

[ ]  Biospecimens

**2. Data collected will include the following personally identifiable and/ or sensitive information:** (check all variables included)

 [ ]  Names of people

 [ ]  Income

 [ ]  Addresses

 [ ]  SS #

 [ ]  Phone numbers

 [ ]  Job title

 [ ]  Age/ Age range

 [ ]  Names of employers

 [ ]  Gender Identity

 [ ]  Types of employers

 [ ]  Marital status

 [ ]  Sexual orientation

 [ ]  Illegal behaviors

 [ ]  Criminal background

 [ ]  Behaviors or habits that may be embarrassing or harmful if divulged to others

 How will these personally identifiable and/ or sensitive data be used in the study?

 **3a. Equity**: Please explain why any category will be *limited or excluded from participation:*

a. Age:

b. Gender/ Gender Identity:

c. Ethnicity/ Race:

d. Socioeconomic status:

e. Sexual orientation:

f. Persons with limited English-language skills:

g. Pregnancy status:

h. Disability status:

i. Health status:

 [ ]  **None of the above subject categories will be excluded from the study.**

 **3b.** Describe your plan (i.e., planned actions, outreach efforts, initiatives, incentives, protocols, etc.) to optimize recruitment of eligible subjects from eligible under-represented groups and/ or minoritized communities into your study.

1. **Inclusion Criteria**: What characteristics must subjects possess to be included in this

study?

1. **Exclusion Criteria**: What characteristics would exclude subjects who are otherwise

eligible from this study?

1. **The total number of subjects who will be contacted to participate:**

 If the study will be conducted at multiple sites, how many subjects will be contacted

 to participate at each site:

1. **The total anticipated number of subjects who will participate based on anticipated**

 **response rate:**

 If the study will be conducted at multiple sites, how many subjects will participate at

 each site based on anticipated response rate:

1. **Does this study specifically target the recruitment of participants who are not**

**fluent in English?**  Yes [ ]  No [ ]

1. **For how long a time will each subject be involved in the study’s intervention or**

 **contributing data to this study?**

 *(If you are using your subjects on more than one occasion, indicate the number of such occasions and their duration.)*

1. **Recruitment Source**. Identify the location from which subjects will be recruited (e.g.,

schools, university campus, fitness facilities, hospitals, etc.).

1. **Recruitment Methods**. Describe **in detail** how subjects will be identified and recruited.

If subjects are identified from private or student records, provide documentation that authorizes the investigators’ access to those records (HIPAA or FERPA forms) as necessary. The official holder of the record must make initial contact of subjects identified through records to initiate involvement in the research protocol unless otherwise approved through other methods.

***Please submit advertisements, flyers, contact letters, telephone contact protocols/scripts, website content, or other recruitment materials proposed for use in subject recruitment as appendix attachments****.*

1. **Coercion or Undue Influence:** Are any of the potential subjects’ clients/ patients, co-

workers, students, or subordinates to any of the investigators? Yes [ ]  No [ ]

*If yes, describe procedures planned to mitigate any actual or perceived coercion or undue influence.*

**E. STUDY LOCATION(S)**

Identify the location(s) and describe the setting(s) of where the subjects will participate in this research (i.e., where will the study procedures be carried out). ***Please submit copies of IRB approvals or letters of cooperation from non-Chamberlain research sites, if necessary, as separate attachments.***

**F. STUDY PROCEDURES**

Please describe in sufficient detail and ***in lay language*** the procedures you will be doing to or with your subjects. **DO NOT PROVIDE BACKGROUND INFORMATION, DATA ANALYSIS PROCEDURES, OR OTHER EXTRANEOUS MATERIAL IN THIS SECTION.**

For faculty conducting research using student research assistants, please describe the planned roles, activities, and preparation of students. (If non-applicable, indicate “N/A”.)

**G. THE INFORMED CONSENT PROCESS**

1. **Overview**: Please describe the process planned to provide subjects information about the study and obtain informed consent from subjects.

1. **Assent**: Describe the process planned to obtain assent from non-emancipated minors or others who are unable to provide legal consent.

1. **Documentation of Informed Consent and/or Assent**: Typically, signed informed consent is required for all subjects who are legally able to provide informed consent. For non-emancipated minors, signed informed consent must be obtained by the minor’s parent or legal guardian. In addition, verbal assent from the minor must be obtained prior to participation if the minor is unable to provide assent. If the minor is capable of reading and understanding information about the study, a signed assent form should be obtained from the minor. **A written copy of the informed consent form must be provided to the subject or the subject’s legally authorized representative.**

**Please check all that apply**:

This study will include:

 Signed informed consent form Yes [ ]  No [ ]

 Parental/ Guardian signed informed consent form Yes [ ]  No [ ]

 Minor assent form Yes [ ]  No [ ]

If any of these forms will be used, please submit a **Microsoft Word** copy with the IRB submission. **DO NOT SEND PDF FILES!** A description of what must be included in consent and assent forms is provided in the IRB Handbook. ***(Note: All forms should be in a reader-friendly format and provided at a reading level appropriate to the subject population. Materials designed for the general public should be provided at approximately an 8th-grade reading level or lower.)***

1. **Request to Waive the Requirement for Documentation of Informed Consent**: The IRB may choose to waive the requirement for the investigator to obtain a signed consent form, if requested, for some or all subjects if it finds any of the following:
	* 1. The study involves no more than minimal risk, **AND** consent would not be needed for the procedure/ intervention if it was occurring outside a research study; or
		2. The major risk in the study is a breach of confidentiality, **AND** the consent form is the only way to link subjects to the study; (subjects or their legally authorized representative will be asked if they want documentation that links the subject to the research and their preferences will be honored); or
		3. The study involves subjects from distinct cultures in which signing forms is not the norm **AND** alternative procedures are in place to document that informed consent was obtained.

***If signed informed consent is NOT obtained, subjects or their legal representatives must receive written information about the study.***

 Does the investigator request the IRB to waive the requirement for documentation of informed consent via a signed informed consent form? Yes [ ]  No [ ]

 If yes, describe the rationale for the waiver with one of the items listed above. Please include a copy of the written information about the study that will be provided to subjects or their legal representatives.

1. **Incomplete Disclosure and Deception:**

Does this study involve:

 a.Incomplete disclosure to subjects at the onset of the study?

 Yes [ ]  No [ ]

 b. Deception of subjects?

 Yes [ ]  No [ ]

 If “Yes” to either, please explain why incomplete disclosure or deception is necessary and describe the procedures you will use to debrief your subjects. ***You must indicate a willingness to allow subjects to withdraw from the study after debriefing and remove their data and all records of their involvement from the study***. Please

 submit a copy of the debriefing script you will use.

1. **Readability of Participant-Facing Materials:** All study-related materials provided to

study participants must be written and formatted appropriately to facilitate comprehension. Please identify the reading level of each participant-facing material (e.g., informed consent forms, study information materials, recruitment materials, etc.) and the measure/ method used to determine the reading level. If the assumed academic level of the study population is unknown, materials should be drafted no higher than an 8th-grade reading level if at all possible. (**Please note**: Many surveys / questionnaires are difficult to assess using common readability measures since survey items are often not written in complete sentences. The IRB exercises the right to challenge the readability of such materials.)

In what language are participant-facing materials written?

The IRB requires that any non-English participant-facing materials be translated by individuals/ services certified or license in medical translation. If applicable, which certified/ licensed translator or service was used to translate materials?

## **H. RISKS AND BENEFITS**

1. **Identification of Risks**. Describe the nature and degree of risk of potential injury, stress, discomfort, invasion of privacy, psychological harm, and other possible risks from all study procedures, drugs and devices (standard and experimental), interviews, and questionnaires.

**2. Management of Risks.** Explain what steps you will take to minimize the risks of harm noted above and protect subjects’ rights and welfare.

**3. Identification of Benefits**. Describe any anticipated direct and/or indirect benefits of this research for individual subjects.

## **I. COSTS, COMPENSATION, AND INCENTIVES**

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 1. **Costs**. Describe any costs that the subject (or third-party payors) may incur as a result of participation in this study (e.g. charges for tests, travel costs, etc.).

2. **Compensation and Incentives**. Will you give subjects gifts, payments, services without charge, or extra course credit for participating in this study? [ ]  Yes [ ]  No.

 *If “Yes”, provide details of this compensation or incentive. Describe how and when*

*compensation and incentives will be provided. Describe how compensation and incentives will be determined and provided should a subject withdraw from the study.*

## **J. CONFIDENTIALITY OF RESEARCH DATA AND PRIVATE INFORMATION**

1. Will you obtain from your subjects any information about their private behavior, economic status, sexual activity, religious beliefs, or other matters which, if made public, might impair their self-esteem or reputation, or could reasonably place the subjects at risk of criminal or civil liability or be damaging to their financial standing or employability? [ ]  Yes [ ]  No

 *If “Yes,” describe the means you will use to ensure that all data are kept secure and confidential until they are destroyed.*

2. How will you ensure the confidentiality of subjects’ private information?

 3. How and to whom will data/ results from this study likely be shared or disseminated?

4. How will you destroy data and records at the end of the study? *(It is the policy of Chamberlain University to store data and study records for seven (7) years in a locked file or password-protected device. After seven (7) years, data and study records may be destroyed. Audiotapes may be erased upon transcription if desired.)*

## **K. CONFLICT OF INTEREST**

The Chamberlain University IRB considers the investigator’s financial interests when evaluating the protection of human subjects. If a financial interest is reported, the Chamberlain University IRB will assess the investigator’s objectivity in communicating risks, selecting subjects, promoting informed consent, and gathering, analyzing, and reporting data. The Chamberlain University IRB may also review disclosures when a financial interest is reported.

 Does any member of the research team have a financial interest in the research or its products or in the study sponsor? [ ]  Yes [ ]  No

 Please explain in detail any financial interest involved (a letter stating the nature of the financial interest may be requested by the IRB):

## **L. ATTACHMENTS**

Please identify which of the following documents are provided with this submission. When submitting, please attach all documents as ***separate*** files. **DO NOT PROVIDE PDF VERSIONS OF IRB APPLICATIONS, INFORMED CONSENT FORMS, ASSENT FORMS, OR RECRUITMENT MATERIALS.**

[ ]  (**Required)**: Documentation of completion of human subjects protection training (Training must have occurred within the past 5 years. Training through NIH or CITI preferred.)

[ ]  Full study protocol

[ ]  Recruitment materials: Identify:

[ ]  Questionnaires/ surveys/ interview questions/ tools: Identify:

[ ]  Informed consent form

[ ]  Parent/ guardian consent form

[ ]  Assent form

[ ]  Written information provided to subjects

[ ]  Permissions/ authorizations/ approvals from IRBs from other institutions: Identify:

[ ]  Other materials: Identify:

**M. SIGNATURES**:

Your signature below indicates that the information provided in this application is correct and that you agree to comply with all federal and institutional policies and procedures designed to protect human subject research. Your signature also acknowledges your understanding of your responsibilities, as a research investigator as noted below.

1. Researchers acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of the Chamberlain IRB.
2. Researchers are responsible for maintaining all study documents, including informed consent forms, in a secure manner approved by the Chamberlain IRB. The Chamberlain IRB may request copies of study documents for auditing or investigation purposes. Researchers must supply documents to the Chamberlain IRB, if requested, in a timely manner.

1. Researchers will promptly report proposed changes in previously approved human subject research activities to the Chamberlain IRB. The proposed changes must not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subjects.
2. Researchers are responsible for reporting the progress of approved research to the Chamberlain IRB, as often as and in the manner prescribed by the Chamberlain IRB on the basis of risks to subjects.
3. Researchers must inform the Chamberlain IRB in the manner prescribed by the Chamberlain IRB that a study has been completed or otherwise closed to further subject recruitment.
4. Researchers will inform the Chamberlain IRB of any other IRBs involved with the review, approval, and/or oversight of the proposed study.
5. Researchers must report and publish research findings and conclusions in a manner that does not permit the identification of individual study subjects.
6. In the event the investigator fails to comply with any terms of the agreement, the Chamberlain IRB has the right to take such action, as it deems appropriate, including termination of this agreement. If the agreement is terminated, the investigators will immediately relinquish all information to the Chamberlain IRB, including materials derived from this information.

A. Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

  ***Hand-signed or legal electronic signature***  Date

B. Supervising Faculty: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*(If this is a Student Application)* ***Hand-signed or legal electronic signature*** Date

***Submit completed and signed application form to irb@chamberlain.edu***