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| crop logo | **Institutional Review Board**  **Clayton State University UC-217**  **2000 Clayton State Blvd, Morrow, GA 30260**  **(678) 466-4100** |

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| CLAYTON STATE UNIVERSITYAPPLICATION FOR APPROVAL OF RESEARCH **WITH HUMAN RESEARCH PARTICIPANT – FULL REVIEW** |

CHECK IRB WEBSITE FOR DETAILED INSTRUCTIONS (http://adminservices.clayton.edu/provost/IRB/). MAIL OR EMAIL APPLICATION TO ADDRESS ABOVE

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| **Dr.**  **Mr.**  **Ms.**    **Principal Investigator**  **Faculty**  **Undergraduate**  **Graduate**  **Staff**   CSU Department AND CSU Mailing Address   **Phone Number (s) & E-Mail**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **\*Signature of Principal Investigator** | **Dr.  Mr.  Ms.**   Co-Investigator **Faculty  Undergraduate  Graduate Staff**   CSU Department AND CSU Mailing Address   **Phone Number (s) & E-Mail**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \*\*Signature(s) of Co-Investigator(s) |
| **\*Your Signature indicates that you have read the guidelines and that you accept responsibility for the research described in this application.  It further attests that you are fully aware of all the procedures to be followed, will monitor the research, and will notify the IRB of any significant PROBLEMS or CHANGES. Student principle investigator must identify faculty advisor as co-investigator or within the body of the protocol description.**  **\*\*Use additional copies of this page as required for additional co-investigators** | |
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| If funding is involved:  (Please list any funding or any possibility of funding. Failure to do so may delay awards.  **Sponsored Program Proposal Number** Name of Funding Agency  **Proposal Deadline**  **Funding amount** |

**TITLE OF RESEARCH:**

NOTE: THE PERSONNEL IN THE HUMAN SUBJECTS OFFICE ARE NOT RESPONSIBLE FOR MEETING RESEARCHER DEADLINES AND CANNOT PREDICT OR GUARANTEE APPROVAL DATES.  SUBMIT AS EARLY AS POSSIBLE TO MEET YOUR DEADLINES.

Date You Would Like to Begin Research:

(at least 4-6 weeks from date of submission to IRB)

Date You Expect to Complete Collection Data:

(Period of approval cannot extend beyond one year; if more time is needed, study must be renewed before end of approval period.)

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| ANSWER ALL 10 QUESTIONS LISTED BELOW. Carefully answer all questions.  Type your responses below each question (*the space will expand to accommodate your answe*r).  Make sure you address each part of the question.  If a question does not apply, answer "Not Applicable."  Do not answer any questions with "see attachments."  *Remember that the Board is made up of people from many different specialties; therefore, we ask that all information be relayed in layman's terms, rather than professional jargon.*  Sign the application cover sheet, and if applicable, have a faculty advisor sign in the appropriate space.  Deliver your original packet (i.e., application and applicable materials) via email to [irb@clayton.edu](mailto:irb@clayton.edu). If unable to submit via email, deliver two copies of the application packet to UC 149.  Do not submit changes until an initial review has been completed; all applications are reviewed as quickly as possible.  Studies may take as long as 6-8 weeks for the review process.  Failure to follow instructions will delay the review process. |

1. **PROJECT ABSTRACT: State rationale and research question or hypothesis (why is this study important and what do you expect to learn?). The abstract will assist the IRB in reviewing your research. The information in the abstract must include a specific description of the procedure(s) involving human participants, the duration of the project, the benefits and risks, and an explanation of how confidentiality and/or anonymity will be controlled.**
2. **DESIGN: Identify your research design and specific factors or variables, conditions or groups in your study, and any control conditions.  Indicate the number of research participants assigned to each condition or group, and describe plans for data analysis.**
3. **RESEARCH PARTICIPANTS:**
   1. **List approximate number of participants**      **, targeted age group**       **(specified in years) and targeted gender**      **;**
   2. **Will any vulnerable populations be used as part of this study? This includes individuals who may have issues understanding information presented to them (e.g., minors, those with psychiatric/ cognitive/ developmental disorders). This also includes individuals who may not be free to choose without coercion (e.g., prisoners). It also includes pregnant women, fetuses, and neonates. If such populations will be used, clearly describe why it is necessary that these particular populations be part of the study.**
   3. **Method of selection and recruitment - List inclusion and exclusion criteria.  Describe the recruitment procedures.  Be sure to include the source(s) of participants.**       
        
      **Is there any working relationship between the researcher and the participants/subjects? Yes** **No****, If yes, explain.**
   4. **Describe any incentives, follow-ups or compensation to be used with individual participants.  This includes payment, gifts, extra credit, etc.  NOTE: Extra credit must not be offered unless there are equal non-research participation options available to students.**
4. **PROCEDURES: State in chronological order what research participant is expected to do and what the researcher will be doing during the interaction.  Indicate the expected duration/time commitment of each research activity.**
5. **MATERIALS: List in sequence all questionnaires and/or tasks given to the research participants.  Attach a labeled copy of all written instruments to each copy of the application.  Each attachment should be identifiable from your description given here.  If an interview will be conducted you must include an interview script or set of questions.**
6. **RISK: The IRB seeks information about risks that a research participant may encounter as a result of data collection and any that may arise in the future as a direct result of the research.  In both cases, carefully describe any such risks and how you plan to minimize them.  The latter must include the availability and limits of treatment for sustained physical or emotional injuries.  (NOTE: any incident directly related to research participation causing significant discomfort, stress or harm should be reported to the IRB immediately):**
   1. **CURRENT RISK: Describe any psychological, social, legal, economic or physical discomfort, stress or harm that might occur to the participants as a result of their research participation.  How will these be held to the absolute minimum?**
   2. **FUTURE RISK: How are all research participants protected from potentially harmful future use of the data collected in this project?  Specify whether the results of participation will be anonymous or confidential (it cannot be both). By anonymous, the IRB means that the researcher does not know the results of the subject's participation. If there is any way for the researcher to identify data as related to a specific individual then only confidentiality may be promised.  Confidential means the researcher may be able to identify a participant's results but will not reveal the participant's identity to anyone else.  Person-to person interviews are never anonymous.  Describe your plans to maintain confidentiality, and state who will have access to the data and in what role. Be sure to provide specific measures planned to remove any direct identifiers, as well as data storage. You must justify retention of identifying information on any data or forms.  DO NOT ANSWER THIS QUESTION WITH "NOT APPLICABLE".**
7. **BENEFIT: State the benefits the participants will gain from the study and the benefits that humankind will receive.  In some cases, the participants will receive credit toward some course requirement. Most, hopefully, will derive educational benefits, especially if they are students.  You must also indicate how your project will benefit humankind, e.g., advance our knowledge of some phenomenon or help solve a practical problem.  As in the RISK section, you must acknowledge the benefits of your study for the IRB to judge whether benefit exceeds risk to the participant.  You MUST list benefits in order for your study to be approved.  Potential benefits of the research must outweigh any risk associated with research participation.**
   1. **Identify any potential beneficial effects on the participants that might result from the research;**
   2. **You must identify any potential benefits that humankind in general will gain from this research.**
8. **CONSENT PROCESS: How will legally effective informed consent be obtained from all research participants?  If any personal health information (PHI) will be collected as part of this study, then information about the type of data that will be collected and how such information will be used/disclosed must be included either as part of the consent document or in a separate PHI consent form. If DECEPTION is used in your study, describe how participants will be deceived, why it is necessary, and how you will debrief the participants.  Provide the IRB with a copy of a written debriefing.  Also include in the consent form a statement such as "In order to make this study a valid one, some information about my participation will be withheld until completion of the study."  In certain instances, such as mail-out surveys, a cover letter may be used, but it should include at least the information shown in the consent form.  This is known as implied consent format.  If written consent will not be obtained, a full explanation of the reasons must be submitted for approval, including assurance that risk to the participant will be minimal.  Be sure to answer this question and supply the appropriate consent document.  Refer to Section VIII of the IRB Guidelines for additional information and the required consent format.  A checklist is available to help you ensure that you have included all the necessary components.**
9. **CONSENT FOR VULNERABLE PARTICIPANTS including MINORS: If minors or other vulnerable participants are involved, outline procedures to obtain their agreement (assent) to participate, in addition to the consent of parent(s) or guardian(s). Describe in any other special procedures that will be used to minimize risk to these vulnerable subjects. When you use MINORS or other VULNERABLE POPULATIONS, informed consent must be obtained from parent(s) or guardian(s), or a clear justification must be provided so that the IRB can determine if they will approve to waive the requirement.   An understandable explanation of your procedures should also be presented to minors and other vulnerable participants, and they should be given an opportunity to volunteer their participation.  This is called "assent" for people who cannot give "legally effective informed consent."  An assent script or form should be attached to the application submitted to the IRB.**
10. **OFF-CAMPUS STUDY SITE(S) – if the activity described in this application involves another institution(s) (EXAMPLES: school, university, hospital, prison, agency)   
    1) List below each institution that will be utilized for/or involved in recruitment and/or data collection.  
    2) Indicate the county and state in which each institution is located.  
    3) Attach a written letter of authorization from each institution or indicate that the authorization is pending.**

Approval Signature of IRB Chairperson Date