DURHAM TECH

Application for Approval of Human Subjects Research

Project Title: _____

Primary Investigator: _____

Research Advisor or Instructor: _____

Co-Investigator(s): _____

Section I: Purpose and Aims

A. Provide an overview of your study that includes a clear description of purpose (i.e., why you would like to conduct this study and what you hope to learn).

B. Provide the specific questions and/or hypotheses you plan to address in your research study.

Section II: Population and Sample(s)

A. Define the population of interest. A population is the entire set of people that you are interested in studying, from whom you plan to draw one or more samples, and to whom you plan to generalize your findings.

B. Does your population include vulnerable human subjects? Vulnerable means reduced in autonomy and includes fetuses, minors (Chapter 48A-2 of North Carolina State law defines a minor as "any person who has not reached the age of 18 years"), pregnant women, prisoners, mentally or physically disabled persons, and others. If yes, explain what vulnerable persons might be included in your population and provide a rationale for their inclusion. If no, indicate NA.

C. Identify the sampling approach you plan to use to recruit and select participants from your population for your sample(s) (e.g., simple random, multistage, convenience, snowball, etc.), then describe in detail how you will use this approach to acquire your sample(s).

D. Describe in detail the process that you plan to use to obtain consent from participants and/or their legally authorized representatives. If you plan to include minors in your study, also describe your plan to obtain assent. If you believe that consent and/or assent are not necessary, explain your rationale.

E. If your participants will include vulnerable human subjects as identified in item II-B, describe any additional safeguards you will use to ensure their voluntary participation. If not applicable, indicate NA.

F. If participants will receive inducements, describe the inducements and your rationale for use. If not applicable, indicate NA.

Section III: Procedures and Risks

A. Provide a detailed and step-by-step description of the research procedures that participants will undergo. Include the time commitment required by participants.

B. Describe the possible biological, psychological, and social risks to participants. Every study includes possible risk even if relatively minor or unlikely and you should not state that no risk exists. At the very minimum you can indicate that no risks are foreseen or anticipated but you must provide a rationale for this claim. Make sure that the statements for potential risk are consistent across this application and your consent form(s).

C. Describe the specific precautions you will take to minimize each of the possible risks to participants identified in item III-B.

D. If your participants will include vulnerable human subjects as identified in item II-B, describe any additional safeguards you will use to protect them from harm. If not applicable, indicate NA.

E. Clearly describe how you will respond if an adverse event occurs in your study. If a participant is harmed, violated, or distressed in some way, what actions will you take to address this event both immediately and afterwards? Note that adverse events might occur during data collection (e.g., emotional distress during testing) or afterwards (e.g., data confidentiality violation).

F. If your study involves deception or withholding of information of any kind, describe the deception or withholding, the rationale for this approach, and your procedure for debriefing participants. If not applicable, indicate NA.

Section IV: Privacy and Data Concerns

A. Provide specific details on how you plan to maintain confidentiality of participants and their information both during the study and after data collection. If you plan to collect data anonymously, clearly explain how your methods allow complete anonymity of participants both during the study and after data collection.

B. Clearly identify all personnel who will interact with participants during the study and/or will have access to collected data. Provide names, role(s) in the study, and level of interaction and/or access, including physical and digital data. EXAMPLE: Jane Smith, primary investigator, will directly interact with potential participants for recruitment, screening, test administration, and debriefing. She will have access to all collected data during and after the study.

C. Describe your storage plans for all physical and digital data. Consider all types of data that you plan to collect such as signed consent forms, completed surveys, transcripts, audio/video recordings, etc. Please be specific with the location(s) of data storage. We don’t need a street address but identification of the town, building, and room is very helpful. Examples might include the locked personal office of [research advisor's name] at [place of employment] in [city, state], or the password-protected personal computer in the home office of [your name] in [city, state].

D. Describe when and how you plan to destroy collected data, again considering all types of collected data (physical and digital). Note that Federal guidelines stipulate a minimum data retention period of

three years after final data collection and your statement should reflect this intent or provide a rationale for early destruction.

Section V: Statements of Agreement

A. The information provided in this application is accurate and complete.
B. I am ultimately responsible for the ethical conduction of this human subjects research study.
C. I will comply with all Durham Tech policies and procedures, the terms of its Federalwide Assurance, and all applicable federal, state, and local laws regarding the protection of human subjects.
D. All individuals involved with this project are qualified to carry out their specified responsibilities and are knowledgeable about the regulations and policies governing this research.
E. I will not begin this project until IRB approval is obtained.
F. Upon approval, I will conduct the project according to the approved protocol and no changes will be implemented without prior approval from the IRB.
G. I will promptly report to the IRB any adverse events involving participants.
H. I will submit a renewal request if the project continues beyond the one-year approval period.
I. I will submit a final report with an executive summary upon completion of the project.
J. I will report by writing and verbally to the IRB chair immediately upon discovery of a confirmed or suspected breach of any protected data. In no event shall the report be made more than two (2) business days after discovery of the breach
K. I have reviewed the College's Communicable Disease Emergency policy (4.5.1) and will adapt my research project to comply with college safety protocols, and communicate those protocols with all personnel and participants.
L. My research advisor and/or instructor has thoroughly reviewed and approved all aspects of my project and this application.
M. Use this space to explain any disagreements indicated to the previous statements and/or to provide any additional information the IRB would find useful in the evaluation of your application. If not applicable, indicate NA.

Section VI: Signature

Provide your full name to identify yourself as the primary investigator of the proposed research study and electronically "sign" this application.

Name (print): _____

Signature: _____

ID# _____ Date: _____