Pfeiffer UNIVERSITY

IRB – Full Application

Investigator Information:						
Principal Investigator: (name of person submitting application)						
Project Title:						
Date Submitted:						
E-mail Address:						
Telephone Number:						
Academic Division:						
Department:						
Relationship to University		Faculty		Student		Staff
Data Collection Start Date:						
Data Collection End Date:						

**** Note: Data collection cannot begin before IRB approval is received.***

Research Ethics Training:		
		NIH/NCI
		CITI
		Other:
Date research ethics training completed:		

Research Description:		
Research Question(s): Please describe the major research questions of the proposed study in language that can be understood by an individual who is not a specialist in the field.		
Major Procedures: What are the major procedures you will use to collect data? How will you cary them out and how will participants be involved? Please include separate information for each different procedure that you plan to use.		
Procedures Identification: Indicate ALL the different procedures planned for this study:		
		Records review – retrospective
		Records review – prospective
		Questionnaires/surveys
		Interviews

		Audiotaping/videotaping
		Social or behavioral intervention
		Behavioral observation
		International research
		Data stored long-term for future use
		Physiological intervention
		Other:
Data Collection: Please list all of the tools that will be used in data collection. Attach copies of each tool being used to this application at time of submission to the IRB. If a draft document is submitted with the application, it should be clearly labeled and a final version must be submitted before data collection begins.		
Outline the planned timing and sequence of the research activities:		
Responsibilities: If there is more than one researcher involved, explain the division of tasks among research staff. What will be the roles and responsibilities?		

Research Setting:

Describe the settings in which research will be carried out:	
List all Pfeiffer sites where the research will be carried out. For each site, explain how the Principal Investigator has access to a population that would allow recruitment of participants.	
List all non-Pfeiffer sites where the research will be carried out, including contact information where applicable. For each site, explain how the Principal Investigator has access to a population that would allow recruitment of participants. What kind of permission is necessary to carry out research at this site? Has the researcher received permission?	

If so, please attach a copy of the permission.	
Do any of the other sites have an IRB? If so, describe the communication with the relevant IRB(s). What data was permission given. Please attach a copy of additional IRB approval(s).	

Research Participants:

Participants: Describe the participants who will be included or recruited in/for this research.		
Special Populations: Indicate if any of the following will be included in this research:		
		Children
		Cognitively impaired
		Institutionalized persons
		Non-English speaking
		Prisoners
		Students (specify school)
		Senior citizens
		Employees
		Pregnant women/fetuses/neonates
		Handicapped
Recruitment: Describe how participants will be recruited for participation in this study. Attach copies of any proposed flyers, pamphlets, print advertisements, scripts for phone calls or on-air ads.		
Compensation: Will participants be offered compensation for participating in the research? If so, describe the terms of the participation agreement and the amount of payment.		

Description of Risk and Plans to Mitigate:

Physical Risks: Describe any physical risks that may be faced by participants in this research. Describe how you will inform participants of the physical risks and what you will do to mitigate these risks or their effects.	

Psychological Risks: Describe any psychological risks that may be faced by participants in this research. Describe how you will inform participants of the psychological risks and what you will do to mitigate these risks and their effects.	
Social Risks: Describe any social risks that may be faced by participants in this research. Describe how you will inform participants of the social risks and what you will do to mitigate these risks or their effects.	
Privacy: Explain provisions to protect privacy interests of participants. This refers to how the Principal Investigator and other investigators will contact participants and/or access private information from or about them during and after their involvement in the research and the participants' expectations of privacy in the project.	

Benefits:

Potential Benefits: Briefly assess the potential benefits to science and/or society which may accrue as a result of this research.	

Informed Consent:

Consent: Will consent be obtained from all participants? If so, how? If not, why?	
Documentation: How will the participants' informed consent be documented?	

Conflict of Interest:

Does any member of the research team (or their immediate family members) have any financial interest in the sponsor of this research	

and/or in the results of this research? If so, please describe those interests clearly.	

Signatures:
Please submit a signed application along with initialed supplements to the chairperson of the IRB. Applications from student researchers will not be reviewed without faculty advisor approval.

Principal Investigator: I will conduct the study identified above in the manner described. If I decide to make any changes in the procedure, or if a participant is injured, or if any problems occur which involve risk or the possibility of risk to participants or others, I will immediately report such occurrences or contemplated changes to the Pfeiffer University Institutional Review Board.	
Principal Investigator's Name:	
Principal Investigator's Signature:	
Date:	

Faculty Advisor (If the Principal Investigator is a Student): I have read and approve of this protocol. I believe this is research as defined by the Department of Health and Human Services (i.e., a systematic investigation designed to develop or contribute to generalizable knowledge) and that the student is competent to conduct the activity as described herein.	
Faculty Advisor's Name:	
Faculty Advisor's Signature:	
Date:	