IRB APPLICATION REVIEW CHECKLIST

Name of Applicant: _____
IRB Reviewer(s): _____
Date of Review: _____

INFORMATION FOR THE REVIEWER: This is a word document, so you may download it to your computer to complete. Each of the components below must be adequately addressed within the application in order to be approved by the IRB. Please indicate whether the PI has given adequate consideration and safeguards to the following areas of concern. Note any concerns, recommendations or questions in the reviewer's comment section for each component.

Save completed reviews as a *WORD* document and return to the designated primary reviewer. The primary reviewer will summarize and compile the reviews and send a copy of the review summary checklist to the applicant for response to any concerns if needed. Concerns and questions noted by reviewer(s) must be satisfactorily addressed by the applicant prior to approval. The primary reviewer will review applicant responses and submit completed review form and proposal application to the IRB Chair or IRB Administrator at hsrc@graceland.edu as indicated.

I.	RESEARCHER INFORMATION	YES	NO	NA
	A. PI is a faculty member or graduate student.			
	B. NIH certification or equivalent training is current within 3 years.			
	C. Potential conflicts of interest are identified and managed.			
Reviewer Comments:				
Applicant Response:				
II.	**GENERAL DESCRIPTION OF THE PROPOSED RESEARCH**	**YES**	**NO**	**NA**
	A. Research question/problem statement is clearly stated.			
	B. Goal(s)/purpose/anticipated outcome(s) are clearly stated.			
	C. Summary includes a brief description of the population, sample, setting, methods and procedure, dissemination/sharing of results.			
	D. Selection of community partners (school, clinical practice site, etc.) is equitable and appropriate.			
	E. Necessary approvals, agreements, and/or contracts with community partners have been obtained and are attached.			
	F. Plan for disseminating/sharing results is appropriate.			
Reviewer Comments:				
Applicant Response:				

III. PARTICIPANTS AND RECRUITMENT	YES	NO	NA
A. An approximate study end date was indicatied.			
B. Population and sample size are appropriate.			
C. Criteria for inclusion/exclusion are equitable.			
D. Recruitment procedures are clearly described.			
E. Role of human subjects and what they will be told about the research are clearly described.			
F. Recruitment of protected populations (including children, facility residents, etc.) is justified.			
G. Additional issues related to protected populations have been adequately addressed (e.g., setting, privacy, rights, etc.)			
H. Recruitment materials (letters of initiation, recruiting scripts, etc.) are attached and appropriate.			
I. Appropriate procedures for obtaining and documenting informed consent from participants are described.			
J. The informed consent document(s) covers the necessary elements for the level of risk and the subject group involved (see below).	**YES**	**NO**	**NA**
1. Statement that the study involves research			
2. Statement of why subject was selected			
3. Disclosure of the identity and all relevant roles of researcher (e.g., PhD candidate, faculty member, facility owner)			
4. An understandable explanation of research purpose			
5. An understandable description of procedures			
6. Expected duration of subject's participation			
7. Statement that participation is voluntary			
8. Statement that refusing or discontinuing participation involves no penalty			
9. Description of reasonably foreseeable risks or discomforts			
10. Information on compensation for participation			
11. Description of how confidentiality will be maintained			
12. Contact info for questions about the research (including researcher, faculty supervisor, and research participant advocate)			
13. Statement that subject should keep/print a copy of the informed consent form			
14. Disclosure of all potential conflicts of interest			
15. Understandable lay person language used throughout consent document and process			
16. Consent document is worded so that participants are not asked to waive their legal rights			
17. If appropriate, indicates that a procedure is experimental (i.e., not a standard treatment or procedure)			

18. If appropriate, disclosure of alternative procedures/treatment			
19. Of appropriate, additional costs to subject resulting from research participation			
Reviewer Comments:			
Applicant Response:			
IV. RESEARCH PROCEDURES and METHODS	**YES**	**NO**	**NA**
A. Methodology & design are justified by the research question.			
B. Data collection procedures are adequately described and include provisions for the protection of participants' identities and contact information.			
C. Adequate provisions to maintain the confidentiality of the collected data are described.			
D. Data collection tools (surveys, questionnaires, interview protocols, spreadsheets, etc.)			
E. Content of data collection tool(s) is appropriate.			
F. Authorship of data collection tools is appropriately recognized.			
Reviewer Comments:			
Applicant Response:			
V. DATA ANALYSIS	**YES**	**NO**	**NA**
A. Variables (quantitative) or phenomenon of interest (qualitative) are adequately described.			
B. Data analysis procedures are appropriate to the design and research question.			
Reviewer Comments:			
Applicant Response:			
VI. POTENTIAL RISKS and BENEFITS	**YES**	**NO**	**NA**
A. Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.			
B. Risks are reasonable relative to anticipated direct benefits to subjects.			
C. Risks are reasonable relative to the importance of the knowledge that may reasonably be expected to result.			
Reviewer Comments:			
Applicant Response:			

RISK LEVEL:

_____ Minimal risk
_____ Greater than minimal risk

RECOMMENDATION:

_____ Approve
_____ Disapprove
_____ Approve with the following stipulations:

HOW OFTEN THIS STUDY SHOUD BE REVIEWED:

_____ 6 months
_____ 12 months
_____ Other:

Projected study end date: _____

(If the study extends beyond the end date, the PI must submit a letter to the IRB requesting an extension)