IRB Investigator Application Checklist

	Application Reference	✔	Notes
Signatures and Basic demographics	All signatures in place?		
	I.A. PI information complete?		
	I.B. Co-investigator information complete?		
	I.C. Student PI information complete, including faculty sponsor information?		
	I.D. Title clear?		
	I.E. Project dates appropriate?		
	I.F. Type of research identified?		
	Study to be published		
	I.G. Cooperating FGCU Department or Outside Entity		
	Letter(s) of cooperation attached?		
	I.H. Collaborating Institution(s) identified, if any?		
	Letter(s) of cooperation attached?		
	I.I. Study sponsored?		
	Sponsor information provided?		
	I.J. Level of review requesting identified?		
	I.K. Training certificates attached/on file with ORSP for all investigators?		
	I.L. Conflict of Interest noted?		

Section II: Study Description

Abstract	**IIAI. Abstract concise, in lay language; clearly describes aims/objectives?**		
	Design scientifically appropriate to answer the question(s)?		
	Importance of the knowledge expected to result from the study clear?		
Synopsis	**II.A.2. Literature review adequate, support need to study issue?**		
	Characteristics of the problem and population clearly described?		
	Bibliography included/attached?		
Hypothesis	**II.A.3. Hypothesis clear, concise?**		
	Outcome measures clearly defined?		
Population	**II.A.4. Vulnerable populations identified?**		
Data Collection	**II.B.1. Type of data collected described?**		
	Description of analysis?		
	II.B.2. If collecting sensitive information such as sexual or illegal behaviors; items identified?		
	II.B.3. If collecting personal identifiers; items identified?		
	II.B.4. All data methods identified?		
	II.B.5. If data collected, transmitted and/or stored via the internet; security measures identified?		

Section II: Study Description Continued

	Application Reference	✔	Notes
Study Population	**II.C.1. Sample size provided?**		
	II.C.2. Solid rationale provided for sample size?		
	Justification for sample size provided?		
	PI have access to required number of subjects?		
	II.C.3. Study inclusion/exclusion criteria clear and reasonable?		
	If recruitment based on gender/race/ethnicity or other social group, protocol justify it?		
	If a vulnerable population, protocol justify their inclusion?		
	Is there the potential for coercion?		
	Sufficient safeguards to protect rights?		
Compensation	**II.C.4. If compensating participants:**		
	II.C.4.a. & b. Type and amount of compensation provided?		
	II.C.4.c. Source of funds provided?		
	II.C.4.d. Disbursement of funds provided?		
	II.C.4.e. Undue influence/coercion addressed?		
	II.C.4.f. Alternative if extra class credit offered?		
Recruitment	**II.D. Recruiting participants?**		
	All recruitment methods identified?		
	Recruitment plan clear, appropriate?		
	If used, recruitment materials attached?		
Informed Consent	**E. Informed Consent**		
	If not required, justification adequate?		
	If subjects lack capacity to consent is consenting process adequate?		
	If studying children, Parent Consent and Child Assent forms attached?		
	If children in study and assent forms not required, justification adequate?		
	II.E.1. Consent process adequately explained?		
	Consent process clearly described?		
	II.E.2. Consent process minimize possibility of coercion?		
	II.E.3 & 4 Plan to evaluate consent process throughout study adequate?		
	II.E.5. Does the study involve the use, creation, disclosure or access to PHI?		
	Appropriate HIPAA authorization attached?		
Protocol	**II.F. Protocol procedures clear and acceptable?**		
	If used, surveys, questionnaires, tests, attached?		
	Instruments/materials easy to understand?		
	Chronological description of procedures participant will be asked to perform described?		
	Description of expected duration of individual's participation (ex. 3 – 20 minute sessions)?		
	If deception used; scientific justification for its use; acceptable plan to debrief participants?		

Section II: Study Description Continued

	Application Reference	✔	Notes
Confidentiality	**G.1. Protections for data confidentiality and adequate o protect participants' privacy adequate?**		
	II.G.2.-3. Location and method of storage for consent forms adequate?		
	If student PI, data stored in faculty office?		
	II.G.4. If individually identifiable info retained, confidentiality adequate?		
	II.G.5. Plan to retain and study records adequate?		
	State data will be maintained for a minimum of 3 years following completion of study?		
	II.G.6. Method of data destruction and data storage mediums adequate?		
Risks	**II.H. All potential risks identified?**		
	II.H.1. Are the risks adequately described?		
	Risks appropriate to study design?		
	II.H.2. Risks minimized by sound research design?		
	Adequate psychological, social or medical monitoring, ancillary care, equipment, or other resources needed to protect subjects?		
	Precautions to decrease likelihood of harm?		
	II.H.3. If appropriate, is there a plan to handle the disclosure of sensitive information to the appropriate authorities?		
	II.H.4. If appropriate, circumstances under which a participant may be terminated by PI discussed?		
Risk/Benefit	**II.I.1. Accurate description of the study's anticipated benefits?**		
	II.I.2. Is the risk/benefit ratio acceptable?		
	Are the risks to participants justified by the anticipated benefits to participants or society?		
Team	**J. Research Team**		
	Adequate information on team members?		

Consent Form: Abbreviated Checklist

If study conducted by a student, identified as such AND Faculty sponsor listed at top of form?		
Form written at 8th grade level		
Statement that refusal to participate will involve no penalty or loss of benefits ?		
Chronological description of procedures participant will be asked to perform		
Description of expected duration of individual's participation (ex. 3 – 20 minute sessions=1 hour)?		
When and where the study will take place?		
How the study sessions will be scheduled?		
Statement on compensation and details of payment?		
Whom to contact if a research-related injury to the participant or questions about the study ?		
Whom to contact for rights as a study participant?		
Statement at bottom re. dated approval stamp on form?		

Attachments

Item	✔	Notes
Informed Consent / Assent documents		
Research instruments (questionnaires, interview questions, surveys, tests)		
Participant recruitment materials (ads, flyers, e-mails, scripts, letters, etc.)		
Letters of cooperation /permission from other sites, participating agencies, etc.		
HIPAA information and authorization / permission forms		
Certificate in human subjects research training if not already on file in ORSP		
Thesis		
Bibliography referenced in Section II.A.2. in a consistent editorial style such as the APA		
Other supporting materials		