IRB REVIEWER CHECKLIST
New Review

Reviewer:	Date:
PI:	Protocol ID:
(Circle One) Exempt Expedited Full	

	E-PROTOCOL SECTIONS AND REQUIREMENTS	Yes	No	N/A
	1. STUDY PROCEDURES			
A	Are all procedures from recruitment, screening, data collection, data analysis, writing of manuscripts accurately described and acceptable?			
B	Are there adequate plans to inform subjects about specific research results that might affect the subject's health and/or decision to continue participation?			
C	Are all recruitment materials attached (e.g., subject pool website posting, flyers letters of introduction) and deemed acceptable after review? (possible coercion such as excessive compensation or unequal relationships should be considered)			
D	Are all other study materials attached (e.g., questionnaires, interview questions, treatment protocol if applicable) and deemed acceptable after review?			
E	Is there adequate time to conduct and complete research proposed?			
	2. DATA ANALYSIS			
A	Does the investigator provide sufficient information to understand the theoretical bases for this study?			
B	Is there adequate description of statistical methods?			
C	Is data collection and study design appropriate to test hypotheses/answer research questions?			
	3. SUBJECT POPULATION			
A	Is subject population described in sufficient detail?			
B	Is rationale for proposed number of subjects reasonable?			

C	Is inclusion and exclusion criteria clearly stated and reasonable?			
D	Are screening procedures described in adequate detail and acceptable?			
E	If potentially vulnerable populations are included (e.g., children, pregnant women/fetuses, patients, students, employees, economically disadvantaged, mentally/cognitively impaired, at risk for losing services), is there adequate justification and measures taken to reduce harm?			
	4. RISKS			
A	Are all foreseeable risks described?			
B	If over minimal risk (risks comparable to those ordinarily encountered in daily life or routine medical care), are risks minimized to the greatest extent possible			
C	If no benefit to subjects, are benefits to society or field articulated?			
	5. BENEFITS/ALTERNATIVES			
A	Do anticipated benefits outweigh the expected risks?			
B	Are alternatives reasonable? If no alternatives, non-participation should be stated as an alternative.			
	6. PROCEDURES TO MAINTAIN CONFIDENTIALITY			
A	Are there adequate provisions to protect the privacy and assure confidentiality of subject?			
B	Has the plan for protecting confidentiality of data been adequately described including storage (location, duration) of data and access by others?			
C	If data is collected/stored via internet, is confidentiality protection plan technologically sound (may require ad-hoc review by tech consultant)?			
D	Are limits to confidentiality (e.g., requirement to report suspected child abuse) and a systematic protocol for disclosure of this information described?			
E	Have all direct and indirect identifiers to be collected been described and justified?			
F	Are methods to protect identifiers or links to identifiers described, and are these methods adequate?			
G	Will identifiers be maintained after completion of study, is it justified, and is data adequately secured?			
H	Will sensitive information be collected/retained? If so, should Certificate of Confidentiality be pursued?			

	7. POTENTIAL CONFLICT OF INTEREST			
A	Are potential conflicts of interests disclosed and described?			
	8. INFORMED CONSENT			
A	Does the protocol describe how researchers will be trained to obtain consent and the setting which consent is obtained (ensuring participant has adequate time to consider participation in an appropriate environment)?			
B	If consent is waived or modified, does waiver meet all criteria specified by federal regulations (*Category I or Category II or Short Form; check the following one that applies*)?			
i	Category I: Research project is conducted by or subject to approval of state/local government officials AND designed to 1) study public benefits or service programs, 2) procedures for obtaining benefits, 3) possible changes in or alternatives to programs, or 4) possible changes in methods or levels of payment for benefits			
ii	Category II: ALL MUST APPLY 1) research involves no more than minimal risk, AND 2) waiver will not adversely affect rights/welfare of subjects, AND 3) research could not be practicably carried out without waiver AND 4) subject will be provided with additional pertinent information after participation			
	Short Form: For subjects with limited education or intellectual capacity (may be used in special circumstances after consulting with GPS IRB Manager)			
C	Are all relevant elements of consent included in consent form or script (*all below need to be checked yes for approval; check N/A if consent does not apply due to waiver and skip to 9*)			
i	Information is in language understandable to participants and reps (age, education, and culturally appropriate)			
ii	No exculpatory language through which participants/reps appear to waive legal rights			
iii	Statement that the study involves research			
iv	Explanation of purposes of research			
v	Expected duration of participation			
vi	Description of procedures (including identification of any that are experimental)			
vii	Description of foreseeable risks/discomforts			
viii	Description of potential benefits (and compensation if included)			
ix	Description of alternatives to participation including non-participation			

x	Description of how identifying information is privatized and maintained			
xi	If more than minimal risk, information on resources to mitigate risks			
xii	Who to contact in adverse event			
xiii	Contact information of the IRB			
xiv	Statement that participation is voluntary and participant can discontinue anytime			
	9. ASSENT			
A	Is assent written in understandable language?			
B	Is official consent obtained through parent/guardian/representative?			
	10.HIPAA			
A	Is PI recruiting at a site that may be covered by HIPAA Privacy Protections?			
B	Has PI received Authorization for research evaluation?			
C	Has PI received Waiver of Authorization?			
	11.ATTACHMENTS			
A	Are all relevant attachments (CITI training certificate, letters of support from community partners, recruitment materials, study instruments/questionnaires, treatment protocol, resource handouts) included and acceptable?			
	12.OTHER CONSIDERATIONS			
A	Are there appropriate resources to conduct research safely?			
B	Is there appropriate monitoring of subjects during and after study (especially if study poses higher risk)?			
C	Are translations of materials necessary, and if so, are translation procedures and resulting documents acceptable?			
D	If deception is involved, is it justified and is an adequate debriefing protocol described?			
E	If appropriate, are counseling referrals or support services provided?			
F	If appropriate, is a Data Safety and Monitoring Plan needed?			
G	Recommended Continuing Review Interval (circle one): 6 mo 12 mo 18 mo other			