IRB REVIEWER CHECKLIST
Continuing Review

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

Guidance
When conducting continuing review, the IRB reviewer should start with the assumption that that the research, as previously approved, satisfied all of the criteria under 45 CFR 46.111 (https://www.hhs.gov/ohrp/regulations-and policy/regulations/45-cfr-46/index.html#46.111) or 21 CFR 56.111 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.111). The IRB reviewer should focus on any new information provided by the investigator, or otherwise available to the IRB, that may alter the IRB's prior determinations, particularly with respect to the IRB's prior evaluation of the potential benefits or risks to the subjects. The IRB reviewer should also assess whether there is any new information that would necessitate revision to the protocol and/or the informed consent document (and if so, review the revised consent document thoroughly to ensure all changes are made; and if no revised consent document is provided, require this from the investigator prior to re-approval). If the IRB reviewer determines that a research activity no longer meets criteria for approval, the IRB reviewer may refer it for a Full Board Review (at which level the Full Board may decide to "disapprove" the study), or the IRB reviewer may require modifications in order to secure re-approval. Other Resources for Continuing Review Guidance are as follows:
https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html
https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294558.pdf

	E-PROTOCOL SECTIONS AND REQUIREMENTS	Yes	No	N/A
	1. CONTINUING REVIEW APPLICATION SUBMISSION			
A	Is the continuing review submitted in a timely manner (prior to IRB approval expiration date)?			

B	Are all consent forms included with the application?			
C	Is an adequate status report on the study's progress provided?			
D	If there any significant info that may change a subject's willingness to participate?			

	2. PROTOCOL CHANGES AND AMENDMENTS			
A	Has the protocol changed since the last IRB Review?			
B	(If applicable) Are requested changes updated in protocol and all appropriate study materials?			
C	Do the requested changes alter the risk/benefit ratio of the subjects?			
	3. PROTOCOL DEVIATIONS AND EXCEPTIONS			
A	Has the PI submitted any new deviations or exceptions since the last IRB review?			
B	(If applicable) Do the reported deviations or exceptions alter the risk/benefit ratio?			
C	Are any protocol changes required or recommended to prevent similar events in the future?			
	4. SERIOUS ADVERSE EVENTS (SAEs) AND UNANTICIPATED PROBLEMS			

A	Have there been any SAEs and/or unanticipated problems reported since the last IRB review?			
B	(If applicable) Have all SAEs/unanticipated problems been reviewed by the IRB?			
C	(If applicable) Do any of these events alter the risk/benefit ratio?			
D	(If applicable) Should other subjects be informed of the events and/or changes to risk/benefit ratio?			
E	Should the consent or protocol be amended to include new information resulting from these events?			
	5. SUBJECT ENROLLMENT			
A	If enrollment is notably slow, is adequate justification/explanation provided to continue with the study?			
B	Is there a notable rate of subject withdrawals?			
	6. PROCEDURES TO MAINTAIN CONFIDENTIALITY			
A	Are there any changes to procedures to maintain confidentiality of data?			
B	(If applicable) Are the revised procedures adequate to protect the privacy and assure confidentiality of subject?			

	7. POTENTIAL CONFLICT OF INTEREST			
A	(If applicable) Are new potential conflicts of interests disclosed and described?			

	8. INFORMED CONSENT			
A	Are there revisions to the informed consent documents?			
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?			
C	Explain the process for how Assent is obtained.			
	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?			
D	Is your HIPAA training completed? Provide year completed.			
	11.ATTACHMENTS			
A	Are all relevant <u>updated</u> attachments (updated CITI training certificate, updated letters of support from community partners, revised recruitment materials, revised study instruments/questionnaires, revised treatment protocol, revised resource handouts) included and acceptable?			
	12.OTHER CONSIDERATIONS			

A	Do risks continue to be minimized and reasonable in relation to the benefits and knowledge to be gained?			
B	Is there continued appropriate monitoring of subjects during and after study (especially if study poses higher risk)?			
C	Were any subject complaints documented for this study to raise concern about whether it should be issued continuing approval?			
D	Are translations of materials necessary in this continuing study phase, and if so, are translation procedures and resulting documents acceptable?			
E	If appropriate, are counseling referrals or support services provided?			
F	If appropriate, is a Data Safety and Monitoring Plan needed?			
G	Should this study be reviewed more frequently than the current schedule (6 months, 1 year)?			
H	Recommended Continuing Review Interval (circle one): 6 mo 12 mo 18 mo other			
I	Have you completed Implicit Bias and/or Title IX training?			

Prepared by Judy Ho, Ph. D., ABPP; IRB Chair; 2018; UPDATED 12/21