CENTRO COMPRENSIVO DE CÁNCER universidad de puerto rico

Construyendo Esperanza

INSTITUTIONAL REVIEW BOARD

CONTINUING REVIEW OF IRB-APPROVED RESEARCH

Please do not complete this form if your study was approved for **Exemption**. If your study requires full board review, please submit this form prior to the next full board meeting scheduled to be on the 4th week of the month. Please note that the deadline for submission is on the 1st of the month. Please ensure that there is a reasonable time for the board to review and approve your application before the study expires.			
Protocol Title			
Principal Investigator		**IRB Approval No.**	
Co-Investigator(s)			
Approval Date for last/previous continuing review *(If this is the 1st continuing review, state "NA")*			
Sponsor/Funding *(If yes, provide name(s) of current funding agency and grant number(s) and submit a copy of the notice of grant approval, if not previously submitted)*			
Does your study require approval of any other committee(s) e.g. Biosafety, Radiation *(If yes, please attach current approval letters.)*		☐ Yes / ☐ No	

Status of Research *(Please check (**x**) all relevant boxes)*	
☐	**Data Analysis Only**
☐	**Research on Hold.** Reasons:
☐	**Research has not Begun.** Reasons:
☐	**Recruiting Subjects. Version No. & Date of Consent Form:** *(Please include a copy of the consent form currently used, if the consent form has been amended since the previous submission)*
☐	**Following up on Subjects**
☐	**Discontinued. Should the IRB inactivate the continuing review of this research?** ☐ **Yes /** ☐ **No**
☐	**Study Completion**
Start Date *(If not started, give estimated date)*	
Completion Date *(If ongoing, give estimated date)**	
Please provide a summary of any amendments or modifications to the research, interim findings, any relevant multi-center trial reports, information about additional risk, and relevant recent literature since the last review. (attached additional page if necessary)	

Section A

Report of Serious Adverse Events (SAE) *(If applicable)*	
Total number of SAEs notified to IRB	
i. Number of SAEs from CCC	
ii. Number of SAEs outside CCC	
iii. Number of local subjects involved	
iv. Number of subjects involved	
Nature of SAEs. Please provide a summary of adverse events and any unanticipated problems involving risks to subjects or others since the last review. *(If none, put "None")*	

Section B

Report of Serious Adverse Events (SAE) *(If applicable)*	
Total number of SAEs notified to IRB	
v. Number of SAEs from CCC	
vi. Number of SAEs outside CCC	
vii. Number of local subjects involved	
viii. Number of subjects involved	
Nature of SAEs. Please provide a summary of adverse events and any unanticipated problems involving risks to subjects or others since the last review. *(If none, put "None")*	

Principal Investigator assurance and signature			
I certify that the information provided is complete and accurate. As Principal Investigator, I have ultimate responsibility for the conduct of this study, the continued ethical acceptability of the project, the protection of the rights and welfare of human subjects.			
Signature of Principal Investigator		**Date**	