

CLINICAL RESEARCH PROTOCOL CONTINUING REVIEW APPLICATION	PROTOCOL NO. _____	PRINCIPAL INVESTIGATOR (Name, Institute/Branch, Address, Telephone): _____
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PROTOCOL TITLE: _____

ACTION REQUESTED:
 Renew -New subject accrual to continue
 Renew -Enrolled subject follow-up only
 Terminate -Protocol discontinued (describe briefly in the attached narrative.)

HAVE THERE BEEN ANY AMENDMENTS SINCE THE LAST REVIEW?
 No
 Yes (Describe briefly in the attached narrative)

SUMMARY OF PROTOCOL SUBJECTS:

NIH	All Other Sites	
_____	_____	Accrual ceiling set by IRB
_____	_____	New subjects accrued since last review
_____	_____	Total subjects accrued since protocol began (if accrual has been less than expected, discuss in the attached narrative.)

REQUESTED ACCRUAL EXCLUSION (Check all that apply):
 None Asian
 Male Black or African American
 Female White
 Children Hispanic or Latino
 American Indian/ Alaskan Native Native Hawaiian or Pacific Islander
 Other: _____

HAVE THERE BEEN ANY CHANGES IN THE SUBJECT POPULATION, RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST REVIEW?
 No
 Yes (Explain changes in the attached narrative)

HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW?
 No
 Yes (Explain changes in the attached narrative)

HAVE ANY UNEXPECTED COMPLICATIONS OR SIDE EFFECTS BEEN NOTED SINCE THE LAST REVIEW?
 No
 Yes (Identify and explain in the attached narrative)

HAVE ANY SUBJECTS WITHDRAWN FROM THIS STUDY SINCE THE LAST IRB APPROVAL?
 No
 Yes (Discuss in the attached narrative)

HAS ANY INFORMATION APPEARED IN THE LITERATURE, OR EVOLVED FROM THIS OR SIMILAR RESEARCH, THAT MIGHT AFFECT THE IRB'S EVALUATION OF THE RISK/BENEFIT ANALYSIS OF HUMAN SUBJECTS INVOLVED IN THIS PROTOCOL?
 No
 Yes (Discuss in the attached narrative)

CHANGE IN PRINCIPAL INVESTIGATOR: No Yes
 Delete: _____
 Add: _____

HAVE ANY ASSOCIATE INVESTIGATORS BEEN ADDED OR DELETED SINCE THE LAST REVIEW?
 No
 Yes (Identify all changes in the attached narrative.)

CHANGE IN MEDICAL ADVISORY INVESTIGATOR: No Yes
 Delete: _____
 Add: _____

CHANGE IN RESEARCH CONTACT: No Yes
 Delete: _____
 Add: _____

IONIZING RADIATION USE (X-rays, e.g., CT; radioisotopes, e.g. PET, etc.):
 None
 Medically indicated
 Research indicated (Complete NIH-88-23a, and attach to this application. Send a copy of entire protocol and NIH-88-23a to Chair, Radiation Safety for concurrent review).
 Research usage HAS NOT changed since originally approved by the IRB and RSC
 Research usage HAS changed since originally approved by the IRB and RSC (explain changes in the attached narrative)

INVESTIGATIONAL NEW DRUG/DEVICE: None IND IDE
 FDA No. _____
 Name: _____
 Sponsor: _____

LIST ALL COMMERCIAL OR OTHER ENTITIES PROVIDING INVESTIGATIONAL DRUG/DEVICE:

HAVE ANY NON-NIH INVESTIGATORS OR SITES BEEN ADDED SINCE THE LAST REVIEW?
 No
 Yes (Identify the persons or sites and describe the collaboration in the attached narrative)

HAVE ANY INVESTIGATORS DEVELOPED EQUITY, CONSULTATIVE, OR OTHER FINANCIAL RELATIONSHIP WITH A NON-NIH SOURCE RELATED TO THIS PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST?
 No
 Yes (Append a statement of disclosure)

The Principal Investigator must attach to this application: (1) a copy of the current consent/assent documents and (2) a memorandum to the IRB Chair that addresses any "yes" responses to the above questions, and that includes a concise statement regarding protocol progress to date and reason(s) for continuing the study.

SIGNATURE	Principal Investigator	Print/Type Name	Date	Send to Accountable Investigator
RECOMMENDATION	Accountable Investigator	Print/Type Name	Date	Send to Branch Chief, or CC Dept. Head of PI
	Branch Chief or CC Dept. Head of P.I.	Print/Type Name	Date	Send to Clinical Director
APPROVALS	Clinical Director	Print/Type Name	Date	Send to Chair, Institutional Review Board
	Chair, For Institutional Review Board	Print/Type Name	Date	Send to Office of Protocol Services, through IRB Protocol Coordinator
COMPLETION	Protocol Specialist	Date		Protocol & Consent Approved Effective