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

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
- ☐ Male
- ☐ Female
- ☐ Children
- ☐ American Indian/ Alaskan Native
- ☐ Other: _____
- ☐ Asian
- ☐ Black or African American
- ☐ White
- ☐ Hispanic or Latino
- ☐ Native Hawaiian or Pacific Islander

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HAVE ANY SUBJECTS WITHDRAWN FROM THIS STUDY SINCE THE LAST IRB APPROVAL?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 _____ Protocol & Consent Approved Effective	Send to Office of Protocol Services, through IRB Protocol Coordinator
COMPLETION	_____ Protocol Specialist	Date _____		