CLINICAL RESEARCH PROTOCOL
<b>CONTINUING REVIEW APPLICATION</b>

PROTOCOL NO.

PRINCIPAL INVESTIGATOR (NIH Employee Name, Inst/Br, Address, Telephone and email):

PROTOCOL TITLE:

PROTOCOL STATUS:  Renew -Recruitment of participants has not yet begunParticipants are currently being recruited or enrolledNo longer recruiting or enrolling participants, subject follow-up onlyParticipants have completed study; study and data analyses ongoingClinical Hold/Recruitment or enrollment of participants suspendedStudy closed. Participants have completed study. Recruitment and data analysis complete.  SUMMARY OF PROTOCOL ENROLLMENT (Aggregate): Only when the NIH is the coordinating site, provide totals and enrollment table for other site.  NIH Site Other Sites Total			IONIZING RADIATION USE (X-rays, e.g., CT; radioisotopes, e.g. PET, etc.) check all that apply:  None Research indicated Research usage HAS NOT changed. Research usage HAS changed. (Explain in summary report)  INVESTIGATIONAL NEW DRUG/DEVICE: None IND IDE *If reporting more than one IND/IDE, list on attached sheet.  FDA No.				
	Accrual ceiling	hy IRB	Name:				
	New subjects a		· -				
	Aggregate tota	ii accrued	Who is the	manufa	cturer of the above entity?		
	recruiting healthy volunteers? involve adults unable to give informed consen	□ No □ Yes at? □ No □ Yes	·		ech Transfer Agreement?		□ Yes
Have analyses by Trials as required	Does the protocol involve a drug/device/product that may lead to you or the NIH receiving payment and/or royalties?  □ No						
<ul><li>a. Have analys</li><li>b. Have signification</li></ul>	☐ Yes (Append a statement of disclosure)						
Have any non-NI □ No	Have there been any amendments since the last review?  ☐ No						
☐ Yes (Ide	☐ Yes (Desc	ribe bri	efly in the attached narrative	/e.)			
sumi WITH THIS REV	Have there been any changes in the informed consent process or documentation since the last review?  □ No						
*Include Name, Inst line. Attach sheet if	/Branch, Telephone, Address, e-mail. Check box if ar necessary.	n NIH Employee and initial		ribe in S	Summary report)		
PRINCIPAL IN	Have there been any changes in the subject population, recruitment or selection criteria since the last review?						
Delete:	□ No						
Add*: □	☐ Yes (Explain changes in the attached narrative.)						
_	L ADJUNCT PRINCIPAL INVESTIGATOR:		Have any unexpected	compli	ications or side effects bee	n noted since th	ne last review?
Delete: Add:	□ No □ Yes (Identify and explain in the attached narrative.)						
	WOODY IN VEGTICATOR			•	•	•	
	VISORY INVESTIGATOR:		Have any subjects wit  ☐ No	hdrawn	from this study since the l	ast IRB approva	al?
	☐ Yes (Discuss in the attached narrative.)						
	SIATE INVESTIGATOR:	<del></del> ,	Has any information a	ppeare	ed in the literature, or evolve	ed from this or s	similar research,
Delete:	that might affect the IRB's evaluation of the risk/benefit analysis of human subjects involved in this protocol?						
Add*: □	□ No □ Yes (Discuss in the attached narrative.)						
RESEARCH C			☐ Yes (Discu	uss in tr	ne attached narrative.)		
Delete:					been distributed to new NII	H investigators?	•
Add*:				Yes Guide l	□ N/A been distributed to new No	n-NIH investiga	itors?
ASSOCIATE I	NVESTIGATOR(S):			Yes	□ N/A		
Delete:	CONFLICTS OF INTEREST REVIEW?						
Add*: □			Date submitted to IC I	DEC:	Date cleared	I by IC DEC:	
SIGNATURE	Principal Investigator	Print/Type Nam	e	Date	Se	end to Accountable	e Investigator
RECOMMENDATION		_		Date		end to Branch Chie	
	Accountable Investigator	Print/Type Nam	e		De	ept. Head of Accou	untable Investigator
	Br Chief/CC Dept. Head of Acct. Invest	Print/Type Nam		Date	Se	end to Clinical Dire	ector
	ы опелоо рерг. пеац от Acct. Invest	Filliv i ype ivam					
APPROVALS	Clinical Director	Print/Type Nam	ne .	Date		end to Chair, Instite eview Board	utional
		. And Type Hain	-	Date		end to Office of Pro	otocol Services
	Chair, For Institutional Review Board	Print/Type Nam	e	Date	Protocol & Consent thr	rough IRB Protoco	
COMPLETION		Date			Approved Effective		
	Protocol Specialist						