



11 **Location for interaction with subjects** (provide name of institution, address, and brief description):

12 **Indicate with a  $\checkmark$  which of the following special populations will be targeted in the research**

Number of subjects to be enrolled at WVU	
Patients	<input type="checkbox"/>
Children (under 18)	<input type="checkbox"/>
Intellectually or emotionally impaired subjects	<input type="checkbox"/>
Elderly subjects (over 65)	<input type="checkbox"/>
Pregnant subjects or fetuses	<input type="checkbox"/>
Prisoners, parolees, incarcerated subjects	<input type="checkbox"/>
Illiterate subjects	<input type="checkbox"/>
Subjects whose primary language is not English	<input type="checkbox"/>
Students or trainees	<input type="checkbox"/>
Employees of institutions associated with the study	<input type="checkbox"/>
Employees or subordinates of investigators	<input type="checkbox"/>

13. **Indicate by a  $\checkmark$  if any of the following items are involved:**

Analysis of records or tissues	<input type="checkbox"/>
Filming, videotaping, or voice-recording of subjects	<input type="checkbox"/>
Questionnaires	<input type="checkbox"/>
Ionizing radiation, either diagnostic or therapeutic	<input type="checkbox"/>
Pathological or diagnostic tissue or fluids	<input type="checkbox"/>
Placental tissue	<input type="checkbox"/>
Fetal tissue	<input type="checkbox"/>
Approved drug or device in "non-FDA-approved" application	<input type="checkbox"/>
Placebo(s)	<input type="checkbox"/>
Deception of subjects	<input type="checkbox"/>
Radiation Safety Approval Date	_____
Institutional Biohazards Approval Date	_____

14 **Method of obtaining informed consent:** (Check all that apply)

written consent form (include a copy in Section C)	<input type="checkbox"/>	how many?	<input type="checkbox"/>
waiver or alteration of consent process (explain in Section C)	<input type="checkbox"/>	how many?	<input type="checkbox"/>
control group consent	<input type="checkbox"/>	how many?	<input type="checkbox"/>

15 **Method of obtaining assent from children (age 7-18) or subjects unable to sign legally valid consent:**

written assent form (include a copy in Section C)	<input type="checkbox"/>	how many?	<input type="checkbox"/>
no assent, under age 7 or severely impaired (explain in Section C)	<input type="checkbox"/>	how many?	<input type="checkbox"/>
waiver or alteration of assent process (explain in Section C)	<input type="checkbox"/>	how many?	<input type="checkbox"/>
control group assent	<input type="checkbox"/>	how many?	<input type="checkbox"/>

16 **Will investigational drugs or devices be used?**

yes  If yes: IND# \_\_\_\_\_ or IDE# \_\_\_\_\_  
no  Manufacturer: \_\_\_\_\_

17 **Source of funding support:** \_\_\_\_\_ Funding status:  Pending

Active OSP # \_\_\_\_\_  
Anticipated funding period: \_\_\_\_\_ Application deadline: \_\_\_\_\_

18 **Will there be any financial remuneration, reward, reimbursement of expenses or other inducements to participate?**

yes  no  (If yes, explain in item 3 of Discussion.)

19 **Will there be any potential added cost to subjects?**

yes  no  (If yes, explain in item 4 of Discussion.)

20 **Will you use a cover letter?**

yes  no  (If yes, attach a copy.) Number of cover letters (versions) used: (Attach copies) \_\_\_\_\_

21 **Will you use a recruitment ad?**

yes  no  (If yes, attach a copy.) Number of recruitment ads (versions) used: (Attach copies) \_\_\_\_\_

21 **Signatures:** (The Board will not review the protocol without these signatures. By signing, department chairs acknowledge approval of this study on the basis of scientific merit and compliance with applicable professional standards; deans and other administrators signify their approval of the use of resources and faculty and student effort on the study. Multi-unit protocols require the signatures of each chair and dean.)

	Name (type or print)	Title	Signature	Date
Dean	_____	_____	_____	_____
Dean	_____	_____	_____	_____
Dept. Chair	_____	_____	_____	_____
Dept. Chair	_____	_____	_____	_____
Hospital Admin.	_____	_____	_____	_____
Faculty Advisor	_____	_____	_____	_____
Other	_____	_____	_____	_____