

## APPENDIX B APPLICATION FOR IRB REVIEW

### I. THE RESEARCH PROPOSAL

Principal Investigator *[the person responsible for the overall conduct of the project]: (Name, Degree, Department, Address, Phone, Human Participant Research Certification)*

Collaborating Investigators: *(for each: Name, Degree, Department, University, Address, Phone, Human Participant Research Certification)*

Study Sites: *(Attach Other IRB Approval if initiated elsewhere)*

Project Title:

Sponsor: (funding agency or department):

Proposed Starting and Ending Dates:

Financial Disclosure filed with the Office of Research \_\_\_\_\_yes \_\_\_\_\_no  
(You may use sponsor or college disclosure form)

Has the Principal Investigator received any direct compensation from the sponsoring company?  
Yes \_\_\_\_\_ No \_\_\_\_\_  
If yes, please explain.

### II. REQUEST FOR EXEMPT STATUS OR EXPEDITED REVIEW

I request this application be considered for: Exempt Status \_\_\_\_\_; Expedited Review \_\_\_\_\_  
The reasons this project qualifies are included on an attached page.

I understand that the IRB Chairperson may grant exempt or expedited review, but, reserves the right to require full Board review of any IRB application.

### III. STUDY POPULATION

Age Range: \_\_\_\_\_ Gender: (Please check one) Males: \_\_\_\_\_ Females: \_\_\_\_\_ Both: \_\_\_\_\_

Special Qualifications: \_\_\_\_\_

Source of Participants: \_\_\_\_\_

Number of Healthy Volunteers: \_\_\_\_\_ Number of Patients: \_\_\_\_\_

Will placebos be used?

IV. PROTECTED GROUPS: Please check any protected groups included in this study.

_____	Children	_____	Mentally Disabled
_____	Pregnant Women	_____	Prisoners
_____	Fetuses		

If the protocol involves children as research participants (not including emancipated minors), read the following:

The consent of both parents is required by regulation where the research involves greater than minimal risk and will not directly benefit the individual child research participant unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. If both parents' consent is not going to be obtained, please explain why:

The assent of the child is required by regulation, if the child is capable of providing such assent (typically age 7-17). If the child's assent is not going to be obtained, please explain why:

If this protocol involves children who are wards of the state or any other agency, entity or institution, advocates must be assigned. Will such children be research participant? YES \_\_\_\_\_ NO

**V. PROTOCOL/CONSENT FORM REFERENCES**

Please indicate the page numbers of the protocol and consent form on which the following topics are addressed:

<u>PROTOCOL</u>		<u>CONSENT FORM</u>	
Page No.	Topic	Page No.	Topic
_____	Purpose	_____	Purpose
STUDY POPULATION		_____	Status of Drug/Device/Procedure
_____	Inclusion/Exclusion	_____	Description of Study
_____	Criteria	_____	Costs
_____	Duration of Participation	_____	Risks
_____	Early Termination Criteria	_____	Benefits
METHODS/PROCEDURES		_____	Alternative to Participation
_____	Drugs and Dosages	_____	Compensation and Injury
_____	Devices	_____	Participant's Assurance
_____	Surgical Procedures	_____	Contact for Questions about Rights as a Research Participant
DATA			
_____	Collection		
_____	Analysis		
_____	Confidentiality		

**VI. INVESTIGATIONAL DRUGS AND DEVICES**

Please list any investigational drugs or devices that will be used in this study:

IND/IDE Number(s): \_\_\_\_\_  
 IND/IDE Name(s): \_\_\_\_\_  
 IND/IDE Sponsor(s)/Manufacturer(s): \_\_\_\_\_

**VII. IONIZING RADIATION**

Does this study involve the use of ionizing radiation? \_\_\_ Yes \_\_\_\_\_ No

If "Yes" please submit one copy of the application form, consent and protocol for approval by the Radiation Safety Committee.