

**CLINICAL RESEARCH PROTOCOL  
INITIAL REVIEW APPLICATION**

PRINCIPAL INVESTIGATOR (Name, Institute/Branch, Address, Telephone):

PROTOCOL TITLE:

ABBREVIATED TITLE (30 characters or less):

PROPOSED START DATE: \_\_\_\_\_ END DATE: \_\_\_\_\_ TOTAL SUBJECTS TO BE ACCRUED: \_\_\_\_\_

**MULTI-SITE COLLABORATION:**

- None  Foreign site(s) only\*  
 Domestic site(s) only\*  Foreign & domestic sites\*  
 \*Include the full name and address of each site and identify whether each holds a Multiple Project or Single Project Assurance. For more information, contact the Office of Human Subjects Research (402-3444).

**REQUESTED ACCRUAL EXCLUSION (Check all that apply):**

- None  Asian or Pacific Islander  
 Male  Black (Not of Hispanic origin)  
 Female  White (Not of Hispanic origin)  
 American Indian/ Alaskan Native  Hispanic  
 Children

\*Attach detailed statement describing the rationale for any requested exclusion(s).

**SUBJECT ACCRUAL CHARACTERISTICS:**

- Median Age  0-20 Yrs.  21-65 Yrs.  66> Yrs.  
 Pediatric  None  <1 Yr.  1-3 Yrs.  4-20 Yrs.  
 Impaired  None  Physically  Cognitively  Both  
 Volunteer  None  Control  Employee  Patient  
 Volunteer Compensation  Yes  No

**NOTE:** Each Protocol must include a discussion of the rationale for subject selection including gender and ethnicity of the population at risk. Recruitment plans and procedures must also be described.

**SPECIAL RESOURCE REQUIREMENTS (Check all that apply)**

- Intensive care  Isolation  
 Pediatric intensive care  Gene therapy  
 Positron Emission Tomography (PET)  Controlled substance(s)  
 Surgery  Prosthetics  
 Transfusion  Gynecological services  
 Bone marrow transplantation

**KEY WORDS** (Enter 5 words, not contained in the protocol title, particularly salient in describing the protocol):

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_
5. \_\_\_\_\_

**PROTOCOL TYPE:**

- Check one. If Clinical Trial, identify Phase.
- Screening  
 Training  
 Natural History  
 Clinical Trial:  
 Phase I  Phase II  
 Phase III  Phase IV  
 (Definitions on Reverse)

**IONIZING RADIATION USE (X-rays, radioisotopes, etc.):**

- None  
 Medically indicated only  
 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.)

**INVESTIGATIONAL NEW DRUG/DEVICE:**

- None  IND  IDE

FDA No. \_\_\_\_\_

Name: \_\_\_\_\_

Sponsor: \_\_\_\_\_

Holder: \_\_\_\_\_

**RESEARCH CONTACT (Name, Address, Telephone, FAX, e-mail):**

\_\_\_\_\_

PATIENT SELF REFERRAL ALLOWED  Yes  No

LIST ON WEB (Check one)  Yes  No

MEDICAL ADVISORY INVESTIGATOR (If necessary):

(Name) (Institute/Branch) (Telephone)

**ASSOCIATE INVESTIGATOR(S) (Name, Institute/Branch, Telephone):**

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_
5. \_\_\_\_\_
6. \_\_\_\_\_
7. \_\_\_\_\_
8. \_\_\_\_\_
9. \_\_\_\_\_

**(Principal Investigator: Be sure to include PRECIS <=400 words as first section of protocol)**

SIGNATURE		Date _____	Send to Accountable Investigator
	Principal Investigator		
RECOMMENDATION		Date _____	Send to Branch Chief, or CC Department Head of Principal Investigator
	Accountable Investigator		
APPROVALS		Date _____	Send to ICD Internal Scientific Review
	Branch Chief, or CC Dept. Head of P.I.		
		Date _____	Send to Clinical Director
	ICD Internal Scientific Review		
		Date _____	Send to Chair, Institutional Review Board
	Clinical Director		
		Date _____	Send to Protocol Coordination Service Center, MRD through IRB Protocol Coordinator
	Chair, Institutional Review Board		
		Date _____	Return to Protocol Coordination Service Center, MRD (10/1N208)
	Director, Clinical Center		
COMPLETION		Date _____	PROTOCOL NO.
	Protocol Specialist		