CLINICAL RESEARCH PROTOCOL
INITIAL REVIEW APPLICATION

PRINCIPAL INVESTIGATOR (Name of NIH Employee, Institute/Branch, Address, Telephone and email):

PROTOCOL TITLE:

ABBREVIATED TITLE (30 characters or less):

PROPOSED START DATE: _____ END DATE: _____ TOTAL SUBJECTS TO BE ACCRUED (Attach target table for Phase 3-4): _____

MULTI-SITE COLLABORATION:
Is this a multi-site collaboration? ☐ Yes (complete this section) ☐ No
Will subjects participate on the protocol at the NIH CC? ☐ Yes ☐ No
Will subjects participate on the protocol at other sites? ☐ Yes ☐ No
If yes, are the sites ☐ Domestic ☐ Foreign ☐ Both
Is NIH the coordinating site?
☐ Yes. For each participating site, provide: Institution name, address, investigator(s), indicate if subjects will be recruited and if they are, include a contact name on attached sheet/protocol face sheet.
☐ No. Coordinating Site is: _____

REQUESTED ACCRUAL EXCLUSION (Check all that apply):
☐ None
☐ Male
☐ Female
☐ Children <18
☐ American Indian/ Alaskan Native
☐ Asian
☐ Black or African American
☐ White
☐ Hispanic or Latino
☐ Native Hawaiian or Pacific Islander

SUBJECT ACCRUAL CHARACTERISTICS:

Minimum Age Permitted _____
Maximum Age Permitted_____
Pediatric ☐ None ☐ <2 Yr. ☐ 2-6 Yrs. ☐ 7-17 Yrs.
Protocol involves healthy volunteers? ☐ Yes ☐ No
Are Healthy Volunteers NIH Employees? ☐ Yes ☐ No
Does the protocol permit self referral? ☐ Yes ☐ No
Will the protocol involve adults unable to give informed consent? ☐ Yes ☐ No

PROTOCOL TYPE: (Check one):
☐ Screening
☐ Training
☐ Natural History - Disease Progression/ Physiology
☐ Natural History - Sample/Data Collection or Analysis (Recruiting Patients)
☐ Natural History - Sample/Data Collection or Analysis (Not Recruiting Patients)
☐ Pharmacokinetics/Dynamics
☐ Clinical Trial: Identify Phase (Check one)
☐ Phase 0 ☐ Phase 1 ☐ Phase 1-2
☐ Phase 2 ☐ Phase 3 ☐ Phase 4

If a Phase 3 Clinical Trial, is analysis for sex, racial/ethnic subgroups required **according to the NIH Policy and Guidelines on the Inclusion of Women and Minorities** as Subjects in Clinical Research? ☐ Yes ☐ No ☐ N/A

KEYWORDS (Words or phrase that describe the protocol.)
1._____
2._____
3._____
4._____
5._____

IONIZING RADIATION USE (X-rays, e.g., CT; radioisotopes, e.g. PET; etc.): check all that apply
☐ 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).

INVESTIGATIONAL NEW DRUG/DEVICE: ☐ None ☐ IND ☐ IDE
*If reporting more than one IND/IDE, list on attached sheet.
FDA No. _____.
IND/IDE Name: _____.
Sponsor: _____.
Who is the manufacturer of the above entity: _____

Does the protocol involve a Tech Transfer Agreement? ☐ Yes ☐ No

Does the protocol involve a drug/device/product that may lead to you or the NIH receiving payment and/or royalties?
☐ Yes (Append a statement of disclosure) ☐ No

Has the NIH IRP COI Guide been distributed to NIH Investigators?
☐ Yes ☐ No

Has the NIH IRP COI Guide been distributed to Non-NIH Investigators?
☐ Yes ☐ No ☐ N/A

CONFLICTS OF INTEREST REVIEW:

Date submitted to IC DEC:_____ Date cleared by IC DEC:_____

Is an Extramural Investigator an ADJUNCT PRINCIPAL INVESTIGATOR? ☐ Yes ☐ No

Name of Adjunct PI: _____

MEDICAL ADVISORY INVESTIGATOR (if necessary) Name, Inst/Branch, Telephone, Address, Email and initial line:

_____

LEAD ASSOCIATE INVESTIGATOR - Name, Inst/Branch, Telephone, Address, Email. Check box if an NIH employee and initial line:

☐ _____

RESEARCH CONTACT: Name, Inst/Branch, Telephone, Address, Email. Check box if an NIH employee and initial line:

☐ _____

ASSOCIATE INVESTIGATOR(S): Name, Institute/Branch, Telephone, Address, Email. Check box if an NIH employee and initial line. Attach list if necessary.

1. ☐ _____
2. ☐ _____
3. ☐ _____
4. ☐ _____
5. ☐ _____

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

SIGNATURE _____ _____ Date _____ Send to Accountable Investigator
Principal Investigator — Print/Type Name

RECOMMENDATION _____ _____ Date _____ Send to Branch Chief, or CC Dept. Head of Accountable Investigator
Accountable Investigator — Print/Type Name

_____ _____ Date _____ Send to Institute/Center Scientific Review Committee
Br. Chief/CC Dept. Head of Acct. Invest. — Print/Type Name

APPROVALS _____ _____ Date _____ Send to Clinical Director
For Institute/Center Scientific Review Comm. — Print/Type Name

_____ _____ Date _____ Send to Chair, Institutional Review Board
Clinical Director — Print/Type Name

_____ _____ Date _____ Send to Office of Protocol Services, through IRB Protocol Coordinator
Chair, For Institutional Review Board — Print/Type Name — Protocol & Consent Approval Completed

PATIENT SAFETY/ RESOURCE REVIEW _____ _____ Date _____ Return to Office of Protocol Services,
Director, Clinical Center — Print/Type Name (10/1S231B)

COMPLETION _____ Date _____ **PROTOCOL NO.** _____
Protocol Specialist

The following data elements are required by the National Library of Medicine for posting on clintrials.gov and meets the registration requirements set forth by the International Committee of Medical Journal Editors (ICMJE) for publishing. http://www.clinicaltrials.gov/

CONDITIONS: Select up to 5 primary diseases or conditions being studied, using NLM Medical Subject Heading (MeSH) controlled vocabulary. The conditions are used to index studies. http://www.nlm.nih.gov/mesh/MBrowser.html

1. _____ 4. _____

2. _____ 5. _____

3. _____

STUDY TYPE: Nature of the investigation. Select Interventional or Observational, in addition to the most appropriate term describing the protocol for each of the corresponding categories.

☐ Interventional Studies

Purpose: Reason for the protocol
☐ Treatment ☐ Prevention ☐ Diagnosis
☐ Educate/Train

Study Design: participant selection
☐ Randomized Trial ☐ Non-randomized Trial

Masking: knowledge of intervention
☐ Open ☐ Single Blind ☐ Double Blind

Control: nature of the interventional control
☐ Placebo ☐ Active ☐ Uncontrolled
☐ Historical ☐ Dose Comparison

Assignment: intervention groups
☐ Single Group ☐ Parallel ☐ Cross-over
☐ Factorial ☐ Expanded Access

Endpoint: primary outcome that the protocol is designed to evaluate
☐ Safety ☐ Efficacy ☐ Safety/Efficacy
☐ Bio-equivalence ☐ Bio-availability
☐ Pharmacokinetics ☐ Pharmacodynamics
☐ Pharmacokinetics/pharmacodynamics

☐ Observational Studies

Purpose: reason for the protocol
☐ Natural History ☐ Screening ☐ Psychosocial

Duration of Sampling: protocol sample in
☐ Longitudinal ☐ Cross-sectional

Selection Method: sample selection
☐ Targeted Population ☐ Random Sample ☐ Case Control

Timing: data collection period
☐ Retrospective ☐ Prospective ☐ Both

COMPLETE FOR INTERVENTIONAL STUDIES ONLY

INTERVENTIONS: Provide up to 10 primary interventions identifying a category for each. Category selections are: Drug, Gene Transfer, Vaccine, Behavior, Device, and Procedure.

	Category	Intervention		Category	Intervention
Ex.:	Drug	AZT	Ex.:	Behavior	Hypnosis
1.			6.		
2.			7.		
3.			8.		
4.			9.		
5.			10.		

OUTCOME MEASURE(S)/ENDPOINT(S): Examples - changes in cardiac output, changes in cognitive function, changes in drug or antibody.
Primary: main outcome representing a primary study question(s). (limit 250 char)

Secondary: outcome(s) of interest to a study, but not representing the primary study question(s). (limit 250 char)