



**III RESEARCH PERSONNEL.** Please provide the information requested below for research administrators, co-investigators and collaborators in this research project.

Last name	First name	Academic Degrees
Professional titles and/or work position within your home institution		
Home institution(s) and department (s) approving this research project		
Mailing address, telephone and fax numbers, e-mail address		
_____		Date _____
Research Administrators' Signature		
_____		Date _____
Co-Investigators' Signature		
_____		Date _____
Collaborator's Signatures		

**REQUIRED ATTACHMENTS**

1. Letters of Study Approval from the Principal Investigator's Home Institution (Department).
2. One copy of the Curriculum Vitae of each member in your research team describing their research qualifications and experience.
3. Research Personnel Information.

#### **IV FUNDING INFORMATION**

Submit three typed copies

Please attach all current and pending grant and contract information descriptors, as follows:

- Funding type (grant, fellowship, training, contract, other)
- Name of Funding Agency
- Principal Investigator on Proposal
- Proposal Identification Number
- Title of Proposal
- Approval period

#### **DESCRIPTION OF RESEARCH PROJECT**

Please attach a comprehensive description of this research project including, in non-technical language, the following information:

- 1) **Background and Purpose of Research**
  - a) A clear justification for the study, its significance in meeting the needs of the country and/or subject population.
  - b) Summarize information on previous studies and on published research on this topic, including nature, extent and relevance of animal studies and other preclinical and clinical studies.
  - c) Explain what hypotheses or research question(s) this activity is designed to answer, its assumptions and its variables. Please state specific objectives and/or aims.
- 2) **Research Ethics.** Provide a definition of the ethical issues and considerations that you believe are implicit to this research project, and when appropriate, explain how you will deal with them.

#### **V) RESEARCH METHODOLOGY AND PROCEDURES**

- 1) **Study Design.** Attach a detailed description of the design of this research study or trial. Please be specific
- 2) **Research procedures** .Attach a detailed description of all study and standard procedures the subjects will undergo as participants in your research project e.g. volumes of blood, size and location of biopsy, drug administration, questionnaires and name of psychological tests etc. Provide this information for each stage of the study (pilot stage, screening procedures, intervention and follow up). **Please use non-technical language.**

**Attach a study flow chart sheet** describing the sequence and timing of all study procedures that will be performed , **if available.**

**RESEARCH METHODOLOGY AND PROCEDURES GUIDELINES.** In answering this question, use the guidelines provided below to name and describe each applicable research procedure involved in this project (Please add new types if needed) .

*(Attach information about the source, amount or dosage to be used)*

- Medications approved by Poison Control Board.
- Investigational Drugs
- Placebo Use
- Herbal Medicines

*(Attach name of the device supplier, a description summary and its uses)*

- FDA approved Devices
- Non significant Risk Devices
- Humanitarian Use Devices
- Investigational Devices

*(Provide information about the type of specimen, amount, use and destination)*

- Blood
- Urine
- Saliva
- CSF
- Tissue
- Others (specify)

V1. **HUMAN SUBJECTS IN THE PROJECT**. Please provide the information requested below in an attachment formatted as shown by the requested information:

- a. **Number of subjects:** What is the total number of subjects (both normal or control subjects, and patients or case subjects) that you will need to meet the objectives of your study.

Total Number ..... Age Range.....

- b. **Type of Subjects:** Please use the table below to describe the subject population according to the type of subjects that will take part in the study. Add other subject types as applicable.

Type of subjects	Number of subjects	Source of subjects	Optional descriptors
Children			
Mentally Challenged			
Pregnant women			
HIV+			
Drug Abusers			
Prisoners			
Elderly			
Refugees			
Adolescents			
Fetal Tissue			
Patents			
Add other subject types as needed			

- c. **Inclusion Criteria:** What specific characteristics potential subjects must have to be included in this study (answer for each group of subjects, if different)
- d. **Exclusion Criteria:** What specific characteristics would exclude potential subjects who are otherwise eligible to be included in this study (answer for each group of subjects, if different)
- e. **Recruitment Strategy:** Explain how you will recruit each group of subjects. Attach the advertisements, flyers, contact letters, telephone protocols, etc.
- f. **Subject Approach:** Explain who will be recruiting, and how they will be approached to participate in the study. Attach letters of Cooperation from agencies, institutions or others involved in subject recruitment.
- g. **Non-Coercive Contact:** Provide an explanation of how you will ensure that subjects will feel free to decline participation in the study and will not be coerced into participation.
- h. **Subject Compensation:** Explain why it is necessary and non-coercive, and how you will deliver gifts, payments and services without charge, course credit or any other form of subject compensation.
- i. **Participation costs:** Explain what payments, if any, the subjects or third-party payers will make while participating in your study.
- j. **Study Location:** Include a statement about the sites (s) where the study will take place. Attach Letters of cooperation.

## V11 RISKS BENEFITS AND ADVERSE EVENTS

Please provide the information requested below in an attachment formatted as shown by the requested information.

- a. **Nature and Degree of Risk:** Describe any possible injury, stress, discomfort, invasion of privacy and other side effects from all study procedures, drugs and devices (both standard and experimental), interviews and questionnaires. Include psycho-social risks as well as physiological risks. Include risks arising from the withholding of standard procedures (Do not refer to the consent form).
- b. **Minimization of Risk:** Specify what steps you will take to protect your subject's rights and welfare. Please describe specific measures applicable to minors, fetuses-in-utero, prisoners, and pregnant women, decisional impaired or economically or educationally disadvantaged subjects.
- c. **Unknown Conditions:** Explain how you will handle the unanticipated discovery of a subject's unknown condition (disease, suicidal intention, genetic predisposition, etc). as a result of study procedures.
- d. **Benefits:** Describe concisely and realistically the benefits of the proposed study for subjects and for society (if none, please state accordingly)
- e. **Adverse Events Treatment.** Explain how the principal investigator will handle adverse events that might result both immediately, and in the future, from study procedures. Please specify under what conditions an adverse event will be referred for treatment by someone outside the research team.
- f. **Adverse Events Facilities.** Please state whether or not you have access to adequate facilities and equipment to handle possible adverse events. If they are not, please outline what measures you will take to handle the occurrence of an adverse event.
- g. **Financial Responsibilities:** Please explain who will be responsible for the treatment of physical injuries resulting from subject participation in study procedures.

## VII CONFIDENTIALITY OF RESEARCH DATA

- a. **Direct Identifiers:** Please state whether or not you will retain any direct identifier of your subject population such as names, ethnicity, patient, hospital, laboratory or claim numbers, address, telephone numbers, locator information, etc.

- b. **Data protection:** Describe how you will protect data against disclosure to the public or to other researchers or non-researchers. Explain who and why other than members of the research team, will have access to the research data (for instance, sponsors, advisers, government agencies, etc.)
- c. **Data Location:** Please state whether or not a copy of the consent form or other study information in the subject's medical or other personal record. Explain why this may be necessary.
- d. **Data Uses:** Please state whether or not you anticipate using any of the research data, information, specimens, etc. from this study for other studies in the future. If yes, please outline the rationale and include this information in the consent form.

## V111 ADDITIONAL INFORMATION

- a. **Radiation Exposure:** Describe, if applicable, any possible exposure of the subject population to radiation procedures (e.g. chest or dental x-rays, fluoroscopy, radioactive tracers or markers). Approval must be obtained for the use of radiation even if they are to be done as part of patient-care. Provide 3 copies of the abstraction letter.
- b. **Private Records;** Describe, if applicable, your access to the subject's medical, academic, educational or any other personal records for screening purposes or during performance of the study. Please specify what type of records and/or information will be abstracted, and provide 3 copies of the data abstraction form.
- c. **Audio-Visual Recordings:** Describe, if applicable, any type of audio-visual recordings or photographs of subjects. Explain how long you will hold them, and who and under what conditions they may be made accessible outside of the research team.

## V111 CONSENT/ASSENT FORMS AND WAIVER

- Written** (Attach copies of all consent and assent form for each subject group)
- Oral** (Attach written scripts of oral consent and assent for each subject group)
- Waiver** (Attach written justification of waiver of consent)