Tulane University Institutional Review Board
Medical/ Human Biological Specimen Research
Project Summary

General Information

1. Title of Study:

2. Tulane's Principal Investigator's Name and Contact Information:

Name:	
Address:	
Phone Number:	
Fax Number:	
Email Address:	

3. Name of Co-Investigators:

4. Name and contact information for the person completing this form:

Name:	
Address:	
Phone Number:	
Fax Number:	
Email Address:	

5. Is the Principal Investigator a Tulane _____student, _____resident, _____fellow?

_____ Yes. Complete Form A.

_____ No

Funding Source

Complete and submit the Grants and Contracts Routing Form with this project summary.

Expedited Review

Expedited review categories may be found at . If you believe your application meets the criteria for expedited review, please indicate which expedited review category(ies) this research falls under: _____

Location

1. Where will research be conducted and/or where will records be accessed? If this is a multi-center study, please provide location information that relates to the Tulane investigator only.

_____ a. Tulane University

_____ b. Tulane University Hospital and Clinic

_____ c. Medical Center Louisiana New Orleans

_____ d. Veteran's Affairs Hospital

_____ e. An international research site (specify) _____

_____ f. Other (specify)_____

Other Reviews

1. Certain kinds of reviews need to occur prior to IRB review. If applicable, please check all that apply and provide documentation of approval with your IRB application:

____ Cancer Research Advisory Board (Contact the CRAB coordinator with questions at 988-6121)

____ Louisiana Cancer Research Consortium (Contact LCRC Chair, Sudesh Srivastav, at 988-2472)

____ Institutional Biosafety Committee (for research involving Recombinant DNA)

____ If research will be conducted at a site outside of the United States, host community approval is required and final IRB approval is contingent upon receipt of this approval.

Please be aware that all other approvals, such as General Clinical Research Center (GCRC), Institutional Animal Care and Use Committee (IACUC), Charity Hospital Research Review Committee, or the VA Hospital Research and Development Committee, must be obtained and maintained by the Principal Investigator. To access these forms, please click here.

Purpose and Rationale for Research Study

1. Please state the research questions and the purpose/specific aims for the research study.

2. Please provide a brief, i.e. less than one page, summary of the background information for this research study.

Research Design and Procedures

1. Briefly describe the research design and research methods you will use. Your answer should include all research procedures related to this study.

2. What are the research subject inclusion/exclusion criteria including gender, age, race, ethnicity, and other specific criteria?

Please check those that apply to your research.

3. Does your research involve the use of : _____a medical device? Complete Form J.

_____a drug? Complete Form K.

4. Does this study involve the use of a placebo?

____ No.

____ Yes. Please describe rescue therapy for subjects receiving placebo, if applicable. Also, if the study design involves withholding proven therapy to conduct a placebo-controlled study, please justify the acceptability of withholding proven therapy.

Research Subjects

1. How many subjects (or subject records) do you plan to enroll (a subject is considered *enrolled* in the study if when s/he signs the consent form or, if a waiver of consent is in place, when the subject or his/her information is accessed for research purposes)?

2. If this is a multi-center study, how many subjects will be enrolled from all centers?

3. Unless this study is a multi-center industry sponsored study, please provide a statistical justification for the chosen sample size.

4. If you plan to target a particular gender, race and/or ethnicity to the exclusion of others, please provide a brief explanation.

5. Some subject groups are particularly vulnerable and require additional protections. Please check off all the groups that will be part of your subject population:

   ____ Pregnant Women/Fetuses (Complete Form B)

   ____ Prisoners (Complete Form C)

   ____ Minors, i.e. persons under the age of 18 (Complete Form D)

   ____ Non-English speakers (Complete Form G)

   ____Temporarily or permanently cognitively impaired persons (Complete Form L)

6. If you plan to enroll subjects who might be particularly vulnerable to coercion (feeling that they are forced to participate in research or will suffer harm if they do not) or undue influence (offering an inducement to participate in research that encourages someone to act against his/her best interest or wishes), please provide a plan to ensure that these subjects are not coerced or unduly influenced to participate in this research study.

Recruitment- ***Please note that finder's fees for subject recruitment and enrollment are not permitted according to Tulane Policy.***

1. Where will subjects be recruited? Describe the way the prospective subjects will be identified and contacted. Provide the IRB with all recruitment materials (e.g., advertisements, recruitment letters, etc.).

2. Who will approach and/or contact prospective research subjects?

3. How will the privacy of prospective research subjects be protected during the recruitment process?

4. Who will obtain the informed consent?

Risks and Benefits to the Subjects

1. Describe the risks and discomforts associated with the research.

2. Describe the measures in place to minimize the risks to subjects.

3. Describe the benefits to the subject that might reasonably result from this research.

4. Describe the benefits to society that might reasonably result from this research.

Data and Safety Monitoring

1. Describe your plan to monitor the data and subject safety for the study. If applicable, describe the expertise represented and the proposed meeting schedule for any body, such as a Data and Safety Monitoring Board (DSMB), that will review data and subject safety information during the study.

Subject Costs and Payments

1. If subjects be paid or receive any sort of compensation for participation in research, please describe the compensation, the distribution strategy, and the what will happen if the subject chooses or must discontinue participation during the study.

2. If subjects will be charged for research-related procedures, please describe below and in the consent form the financial responsibility the subject will undertake.

Data Confidentiality and Subject Privacy

1. Will the data collected for research purposes be identifiable or coded?

   ____ No. Go to next section.

   ____ Yes.

   a. What are the identifiers?

   b. Who will have access to identifiable information?

   c. How will you limit access to identifiable information?

d. How will you protect identifiable information from accidental disclosure?

e. How long will you maintain identifiable information?

Biological Samples

1. If this study will involve the collection of blood, bone marrow, tissue, or any other kind of specimen for research purposes, will you store or bank any of these samples?

   ____ No

   ____ Yes. Complete Form E.

Informed Consent

1. All research participants must provide voluntary written informed consent prior to participation in research activities unless the research meets criteria for a waiver of informed consent. Will you obtain informed consent for this research study?

   ____ No. This requires a waiver of consent, which can only be obtained if the research meets very specific criteria. Fill out Form F to justify a waiver of informed consent.

   ____ Yes. Please create your consent form according to the Tulane Consent Template.

   ____ Yes, but I need a waiver of documentation for informed consent. The documentation waiver can be obtained under limited conditions. Fill out Form F.

2. Does this study involve testing for HIV?

   ____ No

   ____ Yes. The consent form must include information regarding the availability of counseling and mandatory reporting to public health authorities.

HIPAA Authorization: ***This section is only applicable if the principal investigator is part of the Tulane University Medical Group or the research involves the use of information found in the subject's medical record.***

1. Before an investigator may use identifiable health information for research purposes, the research subject must provide written authorization for this use unless the research meets the criteria for a waiver of authorization. Will you obtain written authorization for the use of identifiable information in this study?

   ____ No. This requires a waiver of authorization. Fill out Form F to justify a waiver of authorization.

   ____ Yes. Please create your authorization form according to the Tulane Authorization Template.