

**Tulane University Health Sciences Center  
Consent to Participate in Research**

**Title:**

Randomized, open-label comparison of drug A with drug B for treatment of chronic fatigue in patients with autoimmune disease

**Performance Sites:**

Tulane University Hospital & Clinic  
New Orleans, LA 70112  
(504) 588-5263

**Investigators:**

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Tulane Medical School  
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(504) 588-9999

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Tulane Medical School  
1430 Tulane Avenue  
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**Sponsor:**

The Best Pharma Company  
Green Stamp, New Jersey 07500

**Disclosure of Potential Conflict of Interest:**

The investigator(s) in this study are also healthcare providers. Therefore, they are interested in the knowledge to be gained from this study, and in your well-being. Investigators may obtain salary or other financial support for conducting the research. You are under no obligation to participate in any research study offered to you.

**OR**

The investigator(s) in this study are also healthcare providers. Therefore, they are interested in the knowledge to be gained from this study, and in your well-being. The Department of Cardiology at Tulane Health Sciences Center receives funding from (name of sponsor) to help cover administrative costs such as record keeping, mail and telephone expenses. However, investigators do not receive salary or other financial support from the study sponsors in exchange for conducting this study. You are under no obligation to participate in any research study offered to you.

**Purpose:**

Tell the subject what the study is designed to learn or test.

For example:

*This study is designed to compare A with B in people who have condition X.*

*This study is to evaluate the safety and efficacy of (drug or treatment) in people who.....*

*The purpose of the study is to improve our understanding about.....*

*The purpose of the study is to learn more about.....*

*The purpose of the study is to evaluate the effects of..... .....in people who.....*

*This is a laboratory study designed to test a new method for diagnosing HIV.*

Add 2 or 3 sentences to refine the purpose. Keep it simple and concise. Restrict the text to a statement of only the major purpose(s).

Conclude the section by telling how many subjects will be enrolled.

For example: *Subjects in this study will be patients with uncontrolled seizures. There will be 8000 subjects will be enrolled in this study. (Or, There will be 8000 subjects enrolled in this study; 1000 locally and 7000 internationally.)*

*Participation will last 2 years.*

**Don't's**

Do not list all the study endpoints.

Do not use personal pronouns in this section.

Do not extend an invitation to participate.

Do not use approximations and ranges

**NO:** There will be 30-40 subjects in this study. (State: There will be 40 subjects...)

**Procedures:**

In this section, personal pronouns are appropriate. Use the second person “you”, “your” but please be consistent.

Use bullets and short phrases when possible

Organize, organize, organize

- ▲ Baseline:
- ▲ Randomization:
- ▲ Treatment/Intervention:
- ▲ Follow Up:
- ▲ Early Termination
- ▲ Collection/storage of specimens (labeling, how to withdraw)

The use of tables or flow diagrams may help organize the section and improve readability. Distinguish between routine care and experimental procedures. Specify how subjects are assigned to study arms (randomization), the chance of being assigned to each arm.

Questionnaires: How many, how often, how long will it take to complete these forms?

Test Results: What test results will be given to the subject (including genetic information if it can be confirmed as valid and if the results can be used to maintain or improve health. Referral to genetic counselor, if needed).

**DO NOT:**

Do not use phrases such as “If you agree to participate” or “If you qualify”.

Avoid listing each visit with its attendant procedures.

Do not refer to visit numbers or run-in periods or dose titration phases.

**Potential Risks:**

Identify each procedure and then describe any reasonably foreseeable risks, discomforts, inconveniences and how these will be minimized. Quantify risks using understandable comparisons.

Place the most important risks first. If this is a drug study, first discuss the risks relating to the drug. Minor risks such as blood drawing should be stated at the end of the section. Use lists/bullets when possible.

Don't forget the risk of breach of confidentiality. This is especially important in studies where genetic testing is done; blood or tissue samples are stored; treatment and/or serologic testing for HIV or hepatitis is performed; registries and medical record reviews.

If the study involves disclosure of child abuse or other reportable behaviors, explain the legal requirement to report abuse to relevant authorities. Inform subjects about availability of referral for follow up or treatment.

Include a statement that the subject will be given any new information gained during the course of the study, which might affect her/his willingness to participate.

**Risks to an Unborn Child:**

Include a discussion about the risks of the study for an unborn or nursing child. Specify when pregnancy testing will be done; requirements for birth control; any special considerations for male study participants relating to potential transmission of study drug via semen.

**Potential Benefits:**

If there is a likely benefit, **DO** state the benefit but with the caveat that there is no guarantee.

*There is no guarantee that you will benefit from participating in this research. If the study drug is effective, you may benefit from a cure or improvement in your symptoms (specify what symptoms). (If there is a placebo arm, caution that there may be no benefit if the subject is assigned to receive placebo.) Knowledge learned from this study may benefit you and others in the future.*

If there is no likelihood that subjects will benefit directly, state this clearly.

*There is no benefit to you as a result of participating in this research. Knowledge learned from this study may benefit you and others in the future.*

**DO NOT:**

Do not include payment or other incentives as benefits from participating in research. Do not imply that participants will receive free medical care or medication; or better medical care or medication as a result of participating in research.

**Alternative Treatment:**

Describe any appropriate alternative therapeutic, diagnostic or preventive procedures that should be considered before the subject decides whether or not to participate in the study. If there are no efficacious alternatives, state that an alternative is not to participate in the study.

If prospective subjects are suffering from a terminal illness and there are no alternative treatments available, you should say so; but add that treatment for symptoms and pain control (comfort measures) are available.

If prospective subjects have a chronic, progressive disorder for which no treatment has been demonstrated to be safe and effective, state that as well. But also describe opportunities for managing symptoms, improving ability to function, etc so that it does not appear that the subject will be abandoned if (s)he does not agree to participate.

**Voluntary Participation:**

Participation in research is voluntary. You may choose to participate or not. If you choose to participate but later change your mind, you may withdraw from the study at any time. Refusal to participate or withdrawal from the study will not result in penalty nor any loss of benefits to which you are otherwise entitled.

**Withdrawal from the Study:**

Statement of reasons for which the subject may be taken off study drug/treatment

**Confidentiality:**

(separate from HIPAA)

Discuss how you plan to promote privacy and confidentiality. Clarify whether blood/tissue samples are labeled by name or other personal identifiers; by a coded study number linked to personal identity; by a code not linked to personal identity; or not labeled (anonymous). If certain research results will not be placed in the medical record, specify (for example, results of genetic testing). Indicate that research results will be kept confidential to the extent allowed by law. State that subjects will not be identified in any way if study results are published.

**Certificate of Confidentiality**

**Costs/Payment:**

State whether the subject will be paid or offered other benefits for participating in the study. Specify the amount, when payment will be made and how it will be pro-rated if the subject does not complete all study procedures.

Clarify what the study provides in the way of medication, testing, physician visits, supplies, etc. Clarify what will be charged to the subject or the subject’s insurance company including costs for regular medical care, whatever else is applicable.

Clarify whether study participation will result in additional costs to the subject. If subjects will incur substantial costs from study participation (medication, tests, hospitalization, physician fees, etc) then the amount should be noted before the subject agrees to participate in the study. If there is a question about whether or not insurance will pay for study procedures or medication, the consent should state that someone from the study team will contact the insurance company to verify coverage; and that the coverage will be discussed with the subject before (s)he enrolls in the study.

**Possible Commercial Products:**

If any human materials (tumor tissue, bone marrow, blood, etc) will be stored for uses other than this research; or if samples will be used to establish a cell line which may be shared with other researchers, and which may, in the future be of commercial value, the consent should contain this information. There should be a statement that the researchers and Tulane University may profit financially from this research.

**In the Event of Injury:**

The Administrators of the Tulane Educational Fund, doing business as the Tulane University Health Sciences Center, and the investigators in this protocol will provide necessary medical treatment for any injury or illness which may arise from your participation in this research. However, such treatment will be on a fee for service basis, payable by you or your insurance carrier, if covered by them.

The Tulane University Health Sciences Center does not provide any form of compensation for injury or illness arising from participation in this research, including but not limited to free medical care other than as described in this consent form, if any, payment of lost wages, or compensation for pain and suffering.

Complete information concerning the non-availability of compensation can be obtained from the Office of the Associate General Counsel , Tulane University Health Sciences Center, 1430 Tulane Avenue, LA 70112, (504) 588-5031. Additionally, that office is available to answer questions about subjects’ rights.

**Questions**

If you have questions about the research, you may call Dr.....at .....

**HIPAA Authorization:**

Use addendum. Do not include HIPAA authorization as part of the main consent.

I have read this consent form and volunteer to participate in this research..

\_\_\_\_\_  
Subject Date

\_\_\_\_\_  
Person Obtaining Consent Date

I am unable to read but this consent document has been read and explained to me by \_\_\_\_\_ (name of reader). I volunteer to participate in this research. I also authorize the use of my PHI as described in this consent form.

\_\_\_\_\_  
Patient Date

\_\_\_\_\_  
Witness Date

\_\_\_\_\_  
Person Obtaining Consent Date