LSU Health Sciences Center NEW ORLEANS

**LSUHSC-NO Institutional Review Board**
**Federal Wide Assurance 00002762 Registration # 00000177**

# Information Sheet Clinical Research Application

**This guide is not a fillable**

**Protocol Abstract**
Provide a brief description of your project explaining what, how and why you are conducting the study. This will provide an overall view of the protocol and should be no more than 300 words. The abstract must be in lay language. Styles should be similar to that used in popular science journals such as National Geographic, Science or Smithsonian.

**Protocol Details**
All 17 items must be completed. It will provide an overview of the procedures and the local conduct of the study. The guide is provided in number order that corresponds to the sections in the Protocol Details.

Use bullets or lists where appropriate such as local sites, or risks. The clinical trials website from NIH (clinicaltrials.gov) provides examples of the style of writing for aims and objectives, eligibility criteria, length of study and other specific details of many current protocols. Both pharmaceutical sponsored clinical trials and government funded studies are listed.

## Protocol Details Section Guidance and Definitions

| | |
|---|---|
| **1. Principal Investigator** | Include PI's title and Department/Section. Briefly describe the PI's qualifications and experience to conduct this research. Do not forward a CV unless requested. A complete list of investigators must be included with the application pages.<br><br>For each intervention or treatment that requires special |

| | |
|---|---|
| | skills (arterial cannulation, biopsy, nuclear scans, radiation therapy, etc) identify the responsible investigator. If the PI or the sub-investigators are not experienced with a procedure required in the protocol, describe the arrangements that have been made with other experts. |

| | |
|---|---|
| **2. Protocol Title** | State the Protocol title, Protocol version and date. All protocols must have numbered pages. The titles on all study documents (consent form, application) must be identical.<br><br>Provide the Phase of Study (Phase I, II, III or IV) |

| | |
|---|---|
| **3. Duration of the Study** | State the length of an individual's participation, active intervention and follow-up<br>Provide the anticipated duration of the entire study. |

| | |
|---|---|
| **4. Products or Devices to be studied**<br><br>**Drugs** | |
| *Investigational Drugs* | List all non-approved drugs and state the IND # and the holder of the IND (sponsor, manufacturer or PI)<br>An investigator's brochure must be provided for all non-FDA approved drugs |
| *Approved Drug-New Indication* | Specify what it is originally approved for and the new indication that will be studied in this protocol |
| *Approved Drugs or Products* | Purpose of drug in this study (comparator, rescue medication, etc.). List each product separately |
| **Devices** | State the device name, manufacturer and whether the device is approved for this use<br><br>Provide:<br>a copy of the FDA notification of the Investigational Device Exemption (IDE)<br>**Or**<br>510(k) Clearance<br><br>For Significant Risk Devices state the IDE # and the holder.<br>Provide the manufacturer's brochure.<br><br>If the device is a non-significant risk device provide a statement from the manufacturer. |
| **Humanitarian Use Devices** | Contact the IRB Office. (504) 568-4970 |

| | |
|---|---|
| **5. Purpose of the Study**<br><br>Provide **<u>one</u>** of the following: | |
| Hypothesis | A statement predicting the results of your study. An explanation of the relationship between two or more variables. A prediction of the answer to the research question: |
| Research Question | *Example: The mortality rate from prostate cancer is more than two fold higher in African Americans compared to Caucasian Americans* |
| Aims and Objectives | The purpose is stated in the form of a question.<br>*Example: Does the addition of metronidazole to a post-surgical treatment plan reduce the occurrence of infection?*<br><br>This is a clear statement of the specific purposes of study which identifies the key study variables and their possible interrelationships and the nature of the population of interest.<br>*Example:*<br>*<u>Aim:</u>*<br>*To determine the progression free survival in children with desmoid tumor treated with sulindac and tamoxifen*<br>*<u>Primary Objective</u>:*<br>*To estimate the safety and efficacy of sulindac and tamoxifen in patients with recurrent DT tumor* |

| | |
|---|---|
| **6. Rationale** | State:<br>- Why this study is being done<br>- The importance of investigating the problem<br>- If the study has been done before, are you confirming a past study or is this generating new information<br>- If the study is expected to benefit patients, advance knowledge or influence policy, State why. |

| | |
|---|---|
| **7. Background** | Must support the scientific aims of the research<br>Provide sufficient information in order that the *scientific merit** of the study can be evaluated<br>** Scientific merit is the key component of the assessment of possible benefit* |
| **Provide the following**: | |
| Summary of results of previous studies | Animal studies, Pre-Clinical, Phase I, Phase II, etc. |
| Summary of investigator's experience with off-label use of the product (drug or device) | |
| Summary of relevant literature | Provide this as a list attached to the end of the summary |

| | |
|---|---|
| **8. Study Design** | Overall strategy for answering the research question, objectives or testing the hypotheses.<br>*Briefly describe*:<br><u>Overall Study Design</u><br>Example: Experimental, observational, case-control, survey evaluation, needs assessment, registries, etc.<br>**AND**<br><br><u>Design Methodologies</u><br>Example: Randomized, double-blind, cross-over, multi-center, etc. |

**9. Study Procedures**

Briefly state the current standard of care for the disease under study.

Indicate how the study procedures differ from the standard clinical care or diagnostic techniques

| | |
|---|---|
| Subjects | State the number of subjects to be enrolled<br>---nationally if a multicenter study<br>---locally |
| Setting | Describe the setting in which the research will be conducted. |
| Eligibility | List the 5 main inclusion criteria<br>List the 5 main exclusion criteria |
| Implementation Summary<br>**complete list of procedures must be attached to the application* | Provide the key details: hospitalizations, office visits (how many, how often) length of follow-ups<br><br>Describe the study arms<br><br>Wash-out periods<br><br>Blood draws (frequency and amount) |
| Placebo | Provide justification for the use of placebo or any non-treatment arm<br>*Example: No current effective treatment available, etc.)* |
| Primary Outcome Variables | Indicate what will be measured and how. |
| Data Collection | Indicate how the data will be collected. Provide details on the instruments to be used (e.g. questionnaire), if the instruments were developed for the study and if they are well-validated and/or standardized |
| Duration of Study | State the length of an individual's participation, active intervention and follow-up.<br>Provide the anticipated duration of the entire study. |

**10. Risks**

Major Risks

List major foreseeable risks associated with study participation, include physical, psychological, social, legal or other risk.

The major risks listed in the Investigator's Brochure must be summarized.

State the likelihood and seriousness

*Example: frequent, likely, rare, etc*.

Include the risks of the procedures, e.g. blood draws, angioplasty, x-rays

State any stopping rules related to the frequency of adverse events

Provide any provisions for ensuring medical intervention

*Example: blinded investigator*

Death

Will risk of death be listed in the Informed Consent Document?

*If NO, explain why not*

**11. Benefits**

Provide a realistic summary of the potential benefits to be gained by the individual subjects as well as benefits to society

Describe how this trial will attempt to demonstrate benefit over pre-existing therapies, diagnostics, or current knowledge

*Example: "It is expected that the treatment will result in partial reduction in tumr size in at least 25% of the enrolled subjects."*

As a reminder, reimbursement/payment and free study drugs are not benefits.

**12. Risk to Benefit Ratio**

Explain why these risks are reasonable in relation to anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

**13. Therapeutic Alternatives**

Identify what available alternatives the person has if he/she chooses not to participate in the study.

Explain why these alternatives will not be used.

*Examples: No alternatives exist, current alternatives have proved to be ineffective, research treatment has the potential for being more effective, etc.*

**14. Data Safety Monitoring**

For Industry-Sponsored Trials or Group Trials

Cite the page number /section of the Protocol that provides DSMD information

For Multi-site Trials where PI is the lead Researcher

Provide the plan for management of information re: Unanticipated Problems, Interim results & Protocol modifications

For LSUHSC Investigator Initiated Studies

Provide the plan to monitor findings and adverse events.

**15. Statistical Analysis**

| | |
|---|---|
| Sample Size | |
| Industry Sponsored Trials | Protocols must provide a rationale for the selected size.<br>Briefly state what<br>State the page number or citation for this. |
| LSUHSC-NO investigators | Provide a summary of the how the total sample size was determined and the justification for this number.<br>How will collected data be analyzed<br>*Reminder—a pilot study is not exempt from a brief statistical analysis section* |

**16. Data Storage and Confidentiality**

How will research data be stored and secured

If data will be shared with other investigators, explain why this is necessary

Justify releasing data with identifiers that would permit the recipient investigator to know

or infer the identity of the subject

**17. Costs to Subjects**

Describe and justify any costs that the subject will incur as a result of participation; Subjects should not have to pay for research procedures without possibility of direct benefit.
State one of the following:

[ ] All research related procedures and/or medications will be provided at no charge to the subject and will not be billed to the insurance carrier

or

[ ] The insurance provider will be billed for procedures that are considered standard of care . Subjects will be responsible for SOC charges not covered by their insurance provider.

If there is a significant cost to the subject for study procedures an estimate of costs must be provided in the summary and the Informed Consent Document

<u>Study Charges</u>
A list of study specific treatments and procedures must be attached to the application. The list must:

- indicate what items are specifically for this research study and what are standard of care.
- indicate frequency (e.g. weekly, monthly, at each visit, etc.)
- includes MRIs, blood draws, x-rays, echos, ultrasounds, etc.