**William Carey University (WCU) Institutional Review Board (IRB)**

**Medical Treatment Supplemental Application**

DIRECTIONS: Complete this form in its entirety and submit it along with the “WCU IRB Primary Application” if the Research Project will involve any of the following: (1) obtaining human biological samples, (2) recording height, weight, blood pressure, temperature, or any other externally derived measure, (3) having subjects engage in physical activity, (4) obtaining medical information or history, and/or (5) administering biological, pharmaceutical, herbal, and/or dietary supplemental products to subjects.

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**Part A: Evaluations & Measurements**

**I. Screening and Monitoring Evaluations and Measurements**

1. **Medical Record Review – Include a listing of variables (e.g., DOB, weight, etc.) that will be extracted from medical chart (paper or electronic).**

Response:

1. **Physical Examination – Describe baseline evaluations to be conducted, including medical history, physical examination, demographic characteristics, etc. (i.e., age, gender, race, etc.)**

Response:

1. **Vital Signs – Describe measures that will be made and how they will be made. (e.g., Will blood pressure be measured using an automated device or with an aneroid sphygmomanometer? Which arm will be used? Will participant be sitting or lying down? Will more than one blood pressure measurement be made & averaged?)**

Response:

1. **Laboratory Evaluations – Provide the following information if blood sampling will be performed as part of laboratory evaluations:**
	1. **Hematology (e.g., Hematology testing – such as hemoglobin, hematocrit, RBC count, WBC with differential, etc. – will be performed in the laboratory of choice.)**

Response:

* 1. **Pregnancy (e.g., A urine pregnancy test will be performed for female subjects aged 11 and older, and females under the age of 11 who are physically capable of becoming pregnant.)**

Response:

1. **Other Evaluations & Measures: Describe all other rating scales, tests, psychological tools, laboratory evaluations, etc. not already covered previously.**

Response:

**II. Efficacy Evaluations – If applicable, describe the measures that will be used to assess the efficacy of the Research Project’s intervention. In an observational study, assignment to the intervention is not made by the investigator. Note that the discussion of these evaluations is usually quite detailed. Please address (1) What diagnostic tests, scales, measures, etc. will be utilized to evaluate efficacy? (2) What will be the methods and schedules utilized to implement these diagnostic tests, scales, measures, etc.?**

Response:

**III. Pharmacokinetic Evaluation – If applicable, describe all pharmacokinetic evaluations to be utilized by the Research Project. Please address such issues as the following, along with any other relevant details: (1) What sampling method will be utilized? (2) What will be your parameters? (3) Will you utilize model-dependent or model-independent methods?**

Response:

**IV. Safety Planning**

1. **How will patient safety be prioritized and monitored? Will you utilize vital signs, physical examinations, laboratory data, etc.? Include all steps that will be taken to promote and monitor patient safety.**

Response:

1. **Describe any and all plans and procedures for responding to medical emergencies that might develop during the course of the Research Project.**

Response:

**Part B: Safety Management**

**Part B is an explanation of safety management, including important definitions and processes.**

**Please read carefully, keep *a copy* for your records, and refer to them if necessary in order to follow proper protocol should that become necessary.**

**This copy of Part B is to be initialed by the Principal Investigator (PI) beside all six numerals – indicating that the PI has read and understood its contents – then submitted with Part A.**

***Initials***

**\_\_\_\_\_\_\_ I. Clinical Adverse Events (AE)**

Clinical AEs are to be monitored by the PI throughout a study.

**\_\_\_\_\_\_\_ II. Adverse Event Reporting**

The PI is responsible for recording and reporting unanticipated problems related to research that occur during and after study treatment. Serious adverse effects (SAE) will be reported. It is noted that “All on-site SAEs or related sites will be reported to the IRB in accordance with IRB policies. AEs that are not serious will be summarized in narrative or other format and submitted to the IRB at the time of continuing review”.

When study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of a study (including SAEs), these will be reported to the IRB in accordance with IRB guidelines.

Unanticipated Problems Involving Risks to Subjects. AEs that are not serious, but that are notable and could involve risks to subjects will be summarized in narrative or other clear format and submitted to the IRB at the time of continuing review.

**\_\_\_\_\_\_\_ III. Definition of an Adverse Event (AE), what to report, and where to report**

An adverse event (AE) is any untoward medical occurrence in a subject who has received an intervention (drug, biologic, or other intervention). The occurrence does not necessarily have to have a causal relationship with the treatment. An AE can therefore be any unfavorable or unintended sign (e.g., an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

All AEs will be reported to the institution’s IRB (see subsection V) and noted in the study records and any other required documents. Include

* the nature on the onset,
* date and time of onset,
* determination of non-serious versus serious adverse effects,
* intensity (mild, moderate, severe) of adverse effects,
* duration,
* causality, and
* outcome of the event.

**\_\_\_\_\_\_\_ IV. Definition of a Serious Adverse Effect (SAE), what to report, and where to report.**

An SAE is any adverse drug experience occurring at any dose that results in any of the following outcomes:

* Death,
* A life-threatening event (at risk of death at the time of the event),
* Requires inpatient hospitalization or prolongation of existing hospitalization,
* A persistent or significant disability/incapacity, or
* A congenital anomaly/birth defect in the offspring of a subject.

Important medical events that may not result in death, but be life-threatening, or require hospitalization may be considered a serious adverse drug event when based upon appropriate medical judgment, they may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

A distinction should be made between a serious adverse effect (SAE) and a *severe* adverse effect. A serious adverse effect (SAE) is a major event as described above. A *severe* adverse effect does not necessarily need to be considered serious, i.e. Nausea which persists for several hours may be considered *severe* nausea but not a SAE; however, a stroke that results in only a limited degree of disability may be considered a mild stroke but is quite obviously a SAE.

All SAEs will be reported to the institution’s IRB (see subsection V), and noted in the study records, and on the case report form.

### Relationship of SAE to study drug or other intervention

The relationship of each SAE to the study intervention should be characterized using one of the following terms in accordance with IRB Guidelines: *definitely, probably, possibly, unlikely* or *unrelated*.

**\_\_\_\_\_\_\_ V. IRB Notification of SAEs, AEs, and Other Unanticipated Problems**

The PI will notify the WCU IRB Chair (irb@wmcarey.edu) of all SAEs, AEs, and Other Unanticipated Problems related to the research activity in accordance with the manner and timeline found within the chart below:

|  |  |  |
| --- | --- | --- |
| **Type of Unanticipated Problem** | **Initial Notification (Phone, Email, or Fax)** | **Written Report** |
| All SAEs  | 24 hours | Within 2 calendar days |
| All AEs | 7 days | Within 7 business days |
| Other Unanticipated Problems | N/A | Summary of important Other Unanticipated Problems may be reported at time of continuing review |

* **Follow-Up Report**

If an SAE has not resolved at the time of the initial report and new information arises that changes the investigator’s assessment of the event, a follow-up report including all relevant new or reassessed information (e.g., concomitant medication, medical history) should be submitted to WCU’s IRB. The WCU IRB investigator is responsible for ensuring that all SAEs are monitored until the situation is either resolved or stable.

**\_\_\_\_\_\_\_ VI. Investigator Report of a SAE to Sponsor**

Reporting must be consistent with regulatory or sponsor requirements.