APPENDIX B:

INFORMED CONSENT FORM

[Exact study name, consent form origination or revision date]

Patient Name: _____ Date:_____

Principal Investigator: _____

Co-Investigator (s): _____

Commercial Sponsor: _____

The following information describes this study and the rights and obligations as a participant. The Principal Investigator or one of the co-investigators will answer any questions about the study or this form.

A. TERMS OF THE STUDY:

You have been asked to participate in a clinical research study to _____ _____ *[briefly describe the project].* _____ *[Name of drug, device or procedure]* is an experimental _____ *[drug, device or procedure]* for patients with _____ *[name or description of disease or condition].*

OR

You have been asked to participate in the study because _____ _____ *[describe].* _____ *[Name of drug, device or procedure]* is an experimental _____ *[drug, device or procedure]* being tested by _____ *[name of sponsor].*

You understand that participation in this study will be voluntary and the treatment of your illness is not dependent upon you participating in this study.

The purposes of this study are: *[List study objective in layman's terms**]*

_____
_____
_____
_____

*[In layman's terms**, give a description of the study and the treatment and/or procedures to be administered during the course of the study]* _____
_____
_____
_____

There will be approximately _____*[list number]* participants enrolled in this study at *[list number]* sites around the United States. It is anticipated that you will participate in this research study for _____ *[list anticipated length of study].*

[If applicable, include restrictions that may apply to females of childbearing potential. Standard statement; "If female, you believe that you are not pregnant. If you are of childbearing potential, you are using an adequate form of birth control."] _____
_____
_____
_____

B. RISKS OR DISCOMFORTS TO THE SUBJECT:

[Statement about the known side-effects of study, drug, risks involved in any procedures to be performed and any other discomforts the subject may experience]
_____
_____
_____
_____

Use of _____ *[drug, device, or procedure],* may involve risks to you which are currently unforeseeable.

[Statement about x-rays and/or blood draws(s), if applicable, to include number, frequency, risk and/or severity, explained in layman's terms. Example: "This is equivalent to the same level of radiation exposure as [number] chest x-rays." Also, amount of blood drawn should be compared to easily understandable measurements, i.e. teaspoons, tablespoons or cups] _____
_____
_____
_____

You understand that any side effects should be discussed with _____ *[name of Principal or co-investigator]* and appropriate action will be taken

Patients must understand that this drug and/or treatment _____
_____
_____
_____
_____
_____
_____
_____
_____
_____(***revise as necessary***)
*[example: may have adverse affects on and may produce abnormal development in the unborn fetus. Female patients: you cannot participate in this study if you are pregnant and you must take a pregnancy test to determine if you are pregnant before starting treatment. It is strongly recommended that you **(females)** do not attempt to become pregnant or that you **(males)** do not father a child during the course of this treatment. Please discuss necessary precautions with your physician as well as concerns about future child bearing with your physician **prior** to beginning treatment. **Females:** Please inform your physician immediately if you suspect you have become pregnant and the treatment will be terminated.]*

C. BENEFITS:

_____
_____
_____[*Statement about the benefits that may occur due to participation in the study*].

No promise of beneficial results has been made to you, nor have any guarantees been offered, either formally or implied, that treatment with _____ [*name of drug, device or procedure*] will be successful.

D. AVAILABLE ALTERNATE COURSES OF TREATMENT:

_____
_____
_____
[*Statement about the alternate course(s) of treatment the subject would receive if they were not involved in the study*]

E. CONFIDENTIALITY OF RECORDS:

You understand that your identity and all information pertaining to you that is collected for this study will remain confidential. However, in order to meet the obligations of Federal law, you understand that case records from this study may be subject to review by representatives of _____ [*study sponsor*],

International Cellular Medicine Society Institutional Review Board and authorized Food and Drug Administration or other government regulatory agencies' personnel. You hereby consent to such review and disclosure.

F. MEDICAL TREATMENTS AND COSTS:

You understand that your participation in this study will not increase the cost to you or your insurance company beyond normal costs related to diagnosing and treating your condition.

_____
_____
[*Statement about compensation and terms, if any*]

OR

You will not receive money or any other form of compensation for your participation in this study.

Should a study-related medical problem or injury occur, appropriate medical outpatient care, as determined by your physician, would be provided by _____ [*name of Principal Investigator, primary care physician or other appropriate professional*]. The costs of such medical care, and the costs of any diagnostic tests needed to determine if the problem is study-related, will be paid by _____ [*name of financially responsible party*]. If it is necessary to be treated as an inpatient for a study-related medical problem or injury, you understand _____ [*name of financially responsible party*] will be financially responsible for such medical treatment. You understand that no additional financial compensation will be available for any injury resulting from your participation. This does not constitute a waiver of any rights that you may have under Federal or State laws and regulations.

[*Add or subtract additional information as necessary and appropriate*].

G. AVAILABLE INFORMATION:

You understand that any significant new information developed during the course of this study, which may relate to your willingness to continue as a participant, will be provided to you.

If you have any questions or desire further information with respect to this study, or if you experience a study-related injury, you should contact:

*Principal Investigator's name:*_____
*Address:*_____
*Phone number:*_____

If you wish to contact an impartial third party not associated with this study, you may contact:

Bridgette Lang at 303-429-6448.

H. TERMINATION:

You understand that your participation in this study is voluntary and you are under no obligation to participate. Your decision on whether to participate in the study will in no way impact upon the treatment you will receive. You may refuse to participate or may discontinue at any time during the study without penalty or loss of benefits to which you are otherwise entitled. If you choose not to participate, or to discontinue your participation in this study, _____ [*name of Principal Investigator*] and his/her associates will continue to take care of your illness to the best of their ability.

In addition, you understand that your participation may be terminated by _____ [*name of Principal Investigator*], and/or your physician without regard to your consent, should he/she determine that continued participation would be detrimental to you in any way. You understand that at the completion of the study, you may not be able to continue treatment with _____ [*name of drug, device or procedure*]

I. PATIENT'S AUTHORIZATION AND CONSENT:

You have had the opportunity to ask questions about _____ [*name of drug, device or procedure OR other as appropriate*], and your participation in this study. You have had the questions answered to your complete satisfaction.

You have read and fully understand this consent form. You understand that you should not sign this form if all my questions have not been fully explained or answered to your satisfaction, or if you do not understand any of the words or terms contained in this consent.

You voluntarily choose to participate in the experimental treatment as part of this study and have been given a copy of this consent form for your records.

_____ _____
Signature Date

_____ _____
Witness (if applicable) Date

The subject is unable to consent because: _____

I, therefore consent for the subject:

_____ _____
Signature of next of kin, legal guardian, or authorized representative Relationship to subject