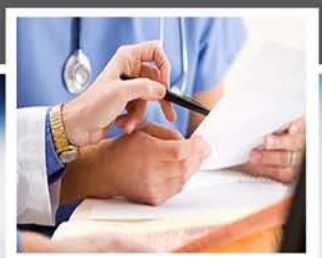
INTERNATIONAL
CELLULAR MEDICINE
SOCIETY

Institutional Review Board: Application for Approval



Defining the future of cell based medicine.

CONTENTS

OVERVIEW

The following guidelines and forms are being provided to assist you in obtaining IRB approval for your research project:

- Summary Information Sheet (form)
- Research Impact Statement (form)
- Elements of the Informed Consent
- Model Informed Consent
- Adverse and Unexpected Event Reporting Requirements
- Adverse Event Report Form
- Continuing Review Requirements
- Continuing Review Form
- Submission Checklist
- Competency Statement

The IRB meets quarterly. Please visit www.cellmedicinesociety.org for the date of the next IRB meeting. The following items must be submitted 15 business days in advance, in order to be considered for review. Please include all elements as outlined in the packet. ***If anything is noted to be incomplete, the study will not be reviewed.*** All documents should be typed originals, no staples please. Please include a completed electronic copy that may be distributed to Board Members for review prior to the meeting.

- A cover letter to the IRB outlining your request
- $1500.00 IRB review fee payable to International Cellular Medicine Society. If denied an approval, the investigator may resubmit the study without submitting another review fee. The investigator must give notice of the resubmission at least 15 days prior to the next meeting and the study will be added to the next agenda.
- Original Summary Information Sheet (enclosed), completed and signed by the Principal Investigator
- Original Research Impact Statement (enclosed), completed and signed by the Principal Investigator. *(Note: If the project involves the use of a hospital service or other facility, the investigator must indicate this. A manager's signature from the impacted service or department is required. Approval will not be given without the completion of this form.)*
- Typed copy of the complete research protocol, including the investigator's brochure, if applicable. Include the following specific point:
- Comparison to current practice
- Expected result
- Any known adverse events
- Explanation of why the research is being done.

Include an original, completed packet including the investigator's brochure, and 2 copies (copies of your investigator's brochure are not necessary). In addition, please include a copy in electronic format.

This IRB requires a certified translation specialist translate all documents requiring translation.

Attendance of the Principal Investigator or sub-investigator is required at the meeting to be available for questions. Please visit www.cellmedicinesociety.org for the next meeting location, date, and time and the investigator will be expected to be present at that time. There is a 10-minute time limit for the presentation. The following points should be included in your presentation:

- Comparison to current practice
- Explanation of why the research is being done
- Expected result
- Any known adverse events

The Principal Investigator will receive notification within 5 days of any action in regard to the study.

If you have any questions or would like additional information, please contact:

David Audley
Executive Director
PO Box 4423
Salem, OR 97302
(503) 884-6590
david@cellmedicinesociety.org

SUBMISSION CHECKLIST

Use this checklist to assure your submission is complete and sign.

☐ **Completed/Signed Summary Information Sheet, Impact Statement and Evidence of Competency forms.**

☐ **Curriculum Vitae for all investigators**

☐ **A one-time fee of $1500.00.**

☐ **Protocol to contain the following:**

- The title of the study with appropriate version dates
- Overview of the proposed treatment including source, isolation and re-implantation methods of the cells used.
- The purpose of the study, indication to be treated including any benefit(s)
- Results/references of previous related research, including, but not limited to support articles from peer reviewed journals
- Subject selection – inclusion/exclusion criteria
- Study design, including a discussion of the research methods
- Description of any/all procedures to be performed and any treatments to be administered
- Copy of outcomes questionnaire to be tracked surveys to be administered (if applicable)
- Provisions for managing adverse reactions
- Explanation of how the data collected will be monitored to ensure the safety of subjects
- Documentation of how the privacy of subjects will be protected
- Documentation of how the confidentiality of data will be maintained
- Informed consent documents(s) **with appropriate version dates**
- Patient candidacy forms with appropriate version dates.

- The investigator's clinical brochure for any investigational drugs or devices, package inserts and advertisements when applicable
- Signed statement from the investigator defining and attesting to their competency in investigational practices.
- HDE submissions need only include the FDA approval letter, instructions for use and pages 3-6 of this packet.
- Methodology for follow-up (frequency, duration, data points collected, loss-to-follow-up)

☐ **All questionnaires and/or interview prompts to be used during the study:**

- Screening
- Data collection
- Follow-up

If anything is noted to be incomplete, the study will not be reviewed at the expected meeting date.

_____ _____

Signature Date

SUMMARY INFORMATION SHEET

Principal Investigator's Name: _____

Sub-Investigator (s): _____

Address: _____

_____

_____

Telephone: _____

Protocol Title: _____

_____

Sponsor (s): _____

Is this study federally funded: ☐ Yes ☐ No Is this an HDE: ☐ Yes ☐ No
If yes, complete pages 3-6 of the application packet only

Risk Category:

☐ "Low Risk" Means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Proposed research under this category does not include the use of drugs, invasive procedures and no major risk of damage. These studies are reviewed at least every twelve months by the IRB.

☐ "Standard Risk" Means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Proposed research under this category is Phase II or Phase III studies in which the drugs that are used have already been tested and research has already been performed on human subjects. There is some knowledge of the drug's toxicity. These studies are reviewed every twelve months or less, at the discretion of the IRB.

☐ "High Risk" Means that the risks of harm anticipated in the proposed research are greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Proposed research under this category are invasive, i.e., transplants; are Phase I studies in which the drug is unknown and the expectations are unknown. These studies are reviewed every twelve months or less, at the discretion of the IRB.

It is my intention to have the study, or aspects of the study performed at the following sites (check all that apply):

☐ Investigator's Office ☐ Other _____

I acknowledge that I am qualified to perform the above requested study by training and experience.

_____ _____

Principal Investigator's Signature Date

RESEARCH IMPACT STATEMENT

Protocol Title: _____

_____

Principal Investigator: _____

Note: If the project involves the use of a service or department, the investigator must indicate this. A manager's signature from the impacted service or department is required. If there is a conflict, this must be resolved by the Principal Investigator and the impacted service or department.

Facility/Service	Services Impacted	In-servicing has been completed (Manager's signature required)	Title

Your signature indicates that you and your staff will comply with all Policies and Procedures of any parties involved, and clinical research rules and regulations

_____ _____

Principal Investigator's Signature Date

EVIDENCE OF COMPETENCY

Note: The investigator must supply evidence attesting to competency and experience in scientific methodology, statistics and investigational practices for the primary researcher. Curriculum vitae may be sufficient.

Protocol Title: _____

_____

Principal Investigator: _____

☐ See attached curriculum vitae (for principal and sub-investigators)

☐ Comments below

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

I acknowledge that I am qualified to perform the above requested study by training and experience.

_____ _____

Principal Investigator Date

CONTINUING REVIEW

Institutional Review Boards are responsible for continuing review of ongoing research to ensure that the rights and welfare of human subjects are protected. FDA regulations require that continuing review of research be conducted at intervals appropriate to the degree of risk, *but not less than once per year*[21 CFR 56.108(a)(1) and 56.190(*f*)]. The frequency and extent of continuing review for each study will be adequate to ensure the rights and welfare of research subjects, and will be documented in the initial approval letter.

A letter of notification will be sent 45 days via receipt mail prior to the review being due if the board has not received your report 30 days prior another reminder will be sent out. "Failure to comply may result in suspension of IRB approval."

The factors considered in setting the frequency of continuing review for any given study may include, but are not limited to:

- The nature of the study;
- The degree of risk involved;
- The vulnerability of the study subject population.

The purpose of continuing review is to review the progress of the entire study, not just changes in it. Continuing review of a study may not be conducted through an expedited review process.

CONTINUING REVIEW REQUIREMENTS:

Documentation:

The following documentation is required, when reporting to the IRB using the continuing review process.

1. A copy of the informed consent document currently in use
2. A written progress report from the clinical investigator, which includes the following information (*see continuing review form included with this sheet*).
    - Number of subjects entered into the study;
    - A summary description of subject experiences (benefits, adverse reactions);
    - Numbers of withdrawals from the study;
    - Reasons for withdrawals;
    - The research results obtained thus far;
    - A current risk-benefit assessment based on study results;
    - Any new information since the IRB's last review

When to report:

The following are the three instances when it is required and/or appropriate to report to the IRB using the continuing review process.

1. *End of approval period:* You will receive a reminder letter approximately one month prior to the end of the study's approval period. You are required to submit a continuing review form along with the appropriate documentation to the IRB for review at their next meeting. For studies on the second or greater review, a $250.00 continuing review fee payable to International Cellular Medicine Society (ICMS). Failure to comply will result in expiration of IRB approval and closure of the study file for International Cellular Medicine Society.

2. *Study completion:* Upon completion of the study, you will be required to submit a final report to the IRB for review. The continuing review form may be used for this purpose.

3. *Minor changes/update:* The continuing review form may be used to inform the IRB of minor changes in ongoing previously approved research during the period for which approval is authorized.

NON-COMPLIANCE

The continuation of research after expiration of IRB approval is a violation of the regulations [21 CFR 56.103(a)]. If the IRB has not reviewed and approved a research study by the study's current expiration date, i.e. IRB approval has expired research activities should stop. No new subjects may be enrolled in the study. By regulation, an IRB has the authority and the responsibility to take appropriate steps such as terminating or suspending approval of research that is not being conducted in accordance with the IRB's requirements.

In the event of termination of the study the sponsor will also be notified.

CONTINUING REVIEW FORM

Protocol Title: _____

_____

Investigator(s): _____

_____

Date study started: _____ Report date: _____

Number of subjects initiated into study (as of report date): _____

Description of subjects' experiences (please include benefits, adverse reactions, withdrawals from research, reasons for withdrawals):

_____

_____

_____

_____

Description of research results obtained thus far:

_____

_____

_____

_____

Current risk-benefit assessment based on your study results thus far:

_____

_____

_____

_____

Reason for review: ☐ Request for continuation ☐ Update ☐ Study completed

Please attach the following items:

1. Additional sheets if space provided is not sufficient
2. Any new information not previously submitted to the IRB for review
3. A copy of the informed consent currently in use
4. A check for $250.00, payable to the International Cellular Medicine Society (ICMS) for studies on the second or greater review.

Principal Investigator's signature: _____

RETURN ALL MATERIALS TO: International Cellular Medicine Society
PO Box 4423
Salem, OR, 97302

IRB QUESTIONS

1. HOW ARE INVESTIGATIONAL PRODUCTS APPROVED?

All investigational products (medications, devices, or radiopharmaceuticals) must be approved by the Institutional Review Board (IRB) which is a committee consisting of physicians, other professionals, and an individual from the community. Without approval, no investigational product should be used.

2. HOW DO YOU KNOW THAT INDIVIDUALS PREPARING, DISPENSING, OR ADMINISTERING AN INVESTIGATIONAL PRODUCT ARE KNOWLEDGEABLE TO DO SO?

The primary investigator is required to educate to all health care professionals involved in the investigational study. Until he or she documents that this has been completed, approval of the study will not be given by the IRB.

3. WHAT ELSE MUST BE DONE BEFORE AN INVESTIGATIONAL PRODUCT IS USED IN A PATIENT?

The primary investigator must discuss the protocol with the patient and/or patient's family and must obtain a consent form.

4. WHAT IS THE RESPONSIBILITY OF THE PHYSICIAN AND ANCILLARY PERSONNEL IN AN INVESTIGATIONAL TRIAL?

Primary Investigator or Designee: Obtains consent from patient and administers investigational drugs.

Ancillary Services: Assures appropriate consent on procedures, may witness consent and identify patient.

5. WHAT IS NEEDED IF THE HOME MEDICATION IS AN INVESTIGATIONAL DRUG?

The physician must supply a copy of the protocol, drug information, and the signed consent form.

APPENDIX A:

ELEMENTS OF THE INFORMED CONSENT

Subject to certain exceptions, no investigator may involve a human being as a subject in research covered by regulation promulgated by the Food and Drug Administration unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or their legal representative sufficient opportunity to consider whether or not to participate, and under conditions that minimize the possibility of coercion or undue influence. The information that is given to the subject or their representative shall be in language understandable to the subject or their representative, and should be translated into their native language if they do not speak English. No informed consent, whether oral or written, may include any exculpatory language through which the subject or their representative is made to waive or appear to waive any of the subject's legal rights, or releases, or appears to release the investigator, the sponsor, the institution, or its agents from liability or negligence.
[21 CFR 50.20]

The requirements for informed consent set out in the regulations apply to all human subjects entering a clinical investigation that commences on or after July 27, 1981.
[21 CFR 50.21]

ELEMENTS OF INFORMED CONSENT *[21 CFR 50.25]*

Basic Elements of Informed Consent

In seeking informed consent, the following information shall be provided to each subject:

The statement: "You understand if you wish to contact an impartial third party not associated with this study, you may contact XXXX, at 123 Main Street, Anytown, AT, 00000 (555)555-5555."

- Statements that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, and a description of the procedures that are experimental.

- A description of any reasonable foreseeable risks or discomforts to the subject.

- A description of any benefits to the subject or to others, which may reasonably be expected.

- A disclosure of appropriate alternative procedures or courses of treatment, if any that might be advantageous to the subject.

- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration and the International Cellular Medicine Society IRB may inspect the records.

- For research involving more than minimal risk, an explanation as to whether any compensation is involved, and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, who will pay for the treatment of a study related problem, and where further information may be obtained.

- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related medical problem of injury.

- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

- The following paragraph:
  "Patients must understand that this drug and/or treatment **(revise as necessary)** 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 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."

Additional Elements of Informed Consent

When appropriate, one or more of the following elements shall also be provided to each subject:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.

- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

- Any additional costs to the subject that may result from participation in the research.

- The consequences of a subject's decision to with draw from the research and procedures for orderly termination of participation by the subject.

- The approximate number of subjects involved in the study.

The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or Local laws which require additional information to be disclosed for an informed consent to be legally effective.
Nothing in these regulations are intended to limit the authority of a physician to provide emergency medical care to the extent that the physician is permitted to do so under applicable Federal, State, or Local law.

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

J. PHYSICIAN DECLARATION:

I certify that I have explained fully to the above patient, the nature and purpose, procedures, possible risks and potential benefits of this research project. I believe I have answered all of the subject's questions, and to the best of my knowledge, I feel that the subject has been adequately informed and has consented.

_____ _____

Physician Investigator Date

_____ _____

Witness (if applicable) Date

APPENDIX C:

ADVERSE EVENT REPORTING

Documentation of a serious adverse event (SAE) or unexpected adverse event (UAE) is a requirement of all study protocols. These events must be reported to the study sponsor, the FDA, and the local Institutional Review Board. Documentation of a SAE, including death due to any cause, is required *regardless of whether or not the SAE is associated with the study treatment.*

DEFINITIONS:

Adverse Event (AE) **–** an adverse event is the development of an undesirable medical condition or the deterioration of a pre-existing medical condition following or during exposure to a pharmaceutical product, medical device, or study-related procedures whether or not considered casually related to the product. An undesirable medical condition can be symptoms (e.g. nausea, chest pain), signs (e.g. tachycardia, enlarged liver) or abnormal results of an investigation (e.g. laboratory findings, electrocardiogram). In clinical studies an AE can include an undesirable medical condition occurring at any time, including run-in or washout periods, even if no study treatment has been administered.

Serious Adverse Event (SAE) **–** One that is fatal, life threatening, or permanently disabling; one that requires or prolongs hospitalization; or results in a congenital anomaly; cancer; or drug overdose or requires treatment to prevent these problems.

Unexpected Adverse Event (UAE) **–** One that is not identified in nature, severity, or frequency in the package insert for the medication.

EVALUATION OF SAE/UAE:

Intensity:

Mild	Usually transient, requiring no special treatment, does not interfere with the patient's daily activities
Moderate	Traditionally introduces a low level of inconvenience or concern to the patient, may interfere with daily activities, usually ameliorated by simple therapeutic measures.
Severe	Interrupt a patient's usual daily activity; traditionally require systemic drug therapy or other treatment.

Relationship to treatment:

Unlikely	Indicates that there is little or no chance the study treatment caused the reported event. Other conditions, including concurrent illnesses, progression or expression of the disease state, or a reaction to a concurrent medication are examples that may explain the reported event.
Possible	Indicates that the association of the event with the study treatment is unknown, however, the event is not reasonably attributed to any other condition
Probable	Indicates that a reasonable temporal sequence exists between the event and treatment administration, and, based upon the investigator's experience, the association of the event with the study treatment seems likely.

PROCESS FOR REPORTING SAE'S/UAE'S

Submit a completed Serious/Unexpected/Adverse Event Report form (enclosed) or a copy of a completed sponsor report form, including all applicable supporting documentation, and the current number of events to the current number of study subjects to the IRB for review. This should be received within 10 days of receipt in the investigators office. Add an acknowledgement field to the bottom of the cover letter we can sign and fax back to you as proof of receipt.

In the event of termination of the study, the sponsor will also be notified by the International Cellular Medicine Society.

APPDENIX D:

SERIOUS ADVERSE EVENT REPORT

Protocol Title:

Investigator(s):

Sponsor:		**Drug/Device/Procedure:**	
# of SAE's at this site:	**Total # of SAE's (all sites):**	**# Of subjects enrolled at this site:**	**Total # of subjects enrolled to date (all sites):**
Patient ID #:		**Date of event:**	

Evaluation classification: ☐ Serious ☐ Unexpected

Intensity: ☐ Mild ☐ Moderate ☐ Severe

Relationship to treatment: ☐ Unlikely ☐ Possible ☐ Probable

Narrative description of the event, including all pertinent clinical history and data associated with the event:

Please attach the following items:

1. Additional sheets if space provided is not sufficient
2. Any new information not previously submitted to the IRB for review
3. A copy of the informed consent currently in use

Principal Investigator's signature: _____

RETURN ALL MATERIALS TO: International Cellular Medicine Society
PO Box 4423
Salem, OR. 97302