



IRB APPLICATION

The International Cellular Medicine Society (ICMS) is an independent, nonprofit organization that has been established to advance the field of adult stem cell medicine through the development of global best practice standards that ensure patient safety, facilitate physician education, and provide peer oversight.

The IRB of the International Cellular medicine Society meets on the second Tuesday of each month. The following items must be submitted by the 1st of the month 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 may not be reviewed.*

- A cover letter to the IRB outlining your request
- \$2,000.00 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. 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 2 to 14 days of any action in regard to the study.

RETURN THIS FORM TO:

International Cellular Medicine Society, PO Box 4423, Salem, OR 97301 USA
info@cellmedsociety.org, www.cellmedsociety.org (503) 884-6590, (877) 900-7372 – FAX
Federal Tax ID#: 75-2985553



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SUMMARY INFORMATION SHEET

Contact Information:

Principal Investigator's Name: _____

Sub-Investigator (s): _____

Address: _____

City: _____

State: _____

Country: _____

Email: _____

Telephone: _____

Study Information:

Protocol Title: _____

Sponsor (s): _____

Condition to be Treated: _____

Source of Cells: _____

Please list the evidence (animal models / peer-review journals) for the use of cell based medicine to treat this condition:

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Is this study federally funded: Yes No

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

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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.

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

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SUBMISSION CHECKLIST

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

- Completed/Signed Summary Information Sheet and Evidence of Competency forms.
- Curriculum Vitae for all investigators
- An initial review fee of \$2,000.00.
- Protocol to contain the following:
 - The title of the study
 - 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 and the confidentiality of data will be maintained
 - Informed consent documents(s)
 - Patient candidacy forms
 - 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. Submissions are due by the 1st of the month.

Signature

Date

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