**STEM CELL RESEARCH OVERSIGHT COMMITTEE** University of California, Davis

## Approval Notice – Annual Renewal

**Approved On**: 05/07/2014 **Expiration Date**: 05/07/2015

**Approval Period:** 05/08/2014 to 05/07/2015

**SCRO Protocol #**: 1085

**Principal Investigator**: Diana Farmer

**Title of Research**: Developing Neural Crest Stem Cells for In Utero Spina Bifida Repair and Spinal Cord Injury Repair

**Department**: Surgery

**Sponsor (Grant #)**: Departmental Funds

**Level of Review**: Expedited Review

**Category of Research**

☐ Research involving the procurement or use of human oocytes

☐ Research involving the use of human embryos

☐ Research intended to create or use a covered stem cell line

☐ Research introducing neural progenitor or other stem cells into the brain of animals

☒ Research introducing a covered stem cell line into animals

☐ Research introducing a covered stem cell line into a live born human

☐ Research using covered stem cell line(s)

☐ Research using non-covered stem cell line(s)

**Additional Information**: Study of potential therapeutics applications of using neural crest stem cells (NCSCs) derived from human placenta and iPSCs to treat spina bifida and spinal cord injuries.

**Cell Line(s):** Neural crest stem cells

The SCRO Committee acknowledges receipt of the following additional approvals and documents:

| | Approval Notice | Protocol # | Expiration | Title |
|---|---|---|---|---|
| IRB | ☐ Not Required<br>☒ Yes | 301243-1 | 01/19/2015 | Biological Examination and Potential Therapeutic Applications of Placental Tissue |
| IACUC | ☐ Not Required<br>☒ Yes | 17955 | 01/24/2015 | In Utero Creation and Surgical Repair of Anatomic Defects |
| BUA | ☐ Not Required<br>☒ Yes | 0999B | 01/23/2015 | Biological Examination and Potential Therapeutic Applications of Placental Tissue |
| MTA | ☒ Not Required<br>☐ Yes | | | |

**As principal investigator for a study involving the use of stem cells, you assume certain responsibilities to the Stem Cell Research Oversight Committee (SCRO). Specifically:**

1. You will conduct this study according to the protocol approved by the SCRO Committee and any other approvals you have obtained from other campus committees. As the principal investigator, you will be accountable for your own research. You will ensure, at all times, that you have the appropriate resources and facilities to conduct this study. You will ensure that all research personnel involved in the conduct of the study have been appropriately trained on the proper conduct of research involving stem cells.

2. Any adverse events must be immediately reported to the SCRO committee according to SCRO policy.

3. Any **changes/additions/revisions** in your research plan must be submitted to the SCRO Committee for review and approval prior to implementation. This includes changes or additions requested by the sponsor and any new personnel associated with the project.

4. Your protocol **must be renewed annually** by submission of the proper application to the SCRO Committee. Failure to submit renewal documents to the SCRO Committee may result in termination of the study by the Committee.

5. **RECORDKEEPING REQUIREMENTS**

    - The PI will maintain records documenting every gamete, somatic cell, embryo donation or product of SCNT that has been donated or used. The record should be sufficient enough to determine the disposition of such materials. The PI will provide these records to the SCRO committee upon request.

    - For research that involves assisted oocyte production or any other alternative method of oocyte retrieval, the investigator shall ensure that a written record is established and maintained to include, but not be limited to, all of the following:

        a. The demographics of subjects, including, but not limited to, age, race, primary language, ethnicity, income bracket, education level, and the first three digits of the zip code of current residence.

        b. Information regarding every oocyte that has been donated or used. This record should be sufficient to determine the provenance and disposition of those materials.

        c. A record of all adverse health outcomes, including, but not limited to, incidences and degrees of severity, resulting from the assisted oocyte production or any alternative method of oocyte retrieval

The SCRO Committee at the University of California, Davis, has **APPROVED** the above referenced study. The SCRO Committee determined all requirements have been adequately met. Should you need to contact the SCRO Committee, please reference the principal investigator's name, protocol number, and the title of the study. Should you have any questions, you may contact Craig Allison, Director of Research Compliance & Integrity at (530) 754-7754 or Craig Allison, Office of Research, 1850 Research Park Dr. Ste. 300, Davis, CA 95618.

Sincerely,

05/07/2014

Craig C. Allison, MPH, JD
Director, Research Compliance & Integrity
Designee signing on behalf of the
Stem Cell Research Oversight Committee Chair

Date