

STATE OF KANSAS

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HOUSE OF REPRESENTATIVES

MR. CHAIRMAN:

I move to amend **SB 199**, as amended by House Committee, on page 1, in line 10, by striking all following "(2)"; by striking all in lines 11 and 12;

In line 13, by striking "(3) facilitate" and inserting "collaborate with Kansas City, Wichita, Omaha and other midwest region university, hospital and cell manufacturing facilities to arrange";

And by redesignating paragraphs accordingly;

Also on page 1, in line 15, by striking "partner and"; in line 21, after "cells" by inserting "where appropriate"; following line 29, by inserting:

"(b) Where appropriate, the center may serve as a core facility to produce clinical grade stem cells from adult tissues, cord blood and related materials for use in clinical trials and therapies.

(c) (1) The rules of governance and administration then otherwise applicable to the performance of education, fundraising, clinical practice, education, human resources, clinical trials, and fee-for-service arrangements at the university of Kansas medical center shall apply to the activities of the center, including, but not limited to, university policies of risk management and compliance in these areas: Human subjects and conflict of interest.

(2) In addition, as a condition of producing clinical grade stem cells by the center for use in humans or the conducting of clinical trials at the university of Kansas medical center involving clinical grade stem cells produced by the center, the center shall demonstrate to the satisfaction of the administration of the university of Kansas medical center and where appropriate the administration of the university of Kansas hospital authority that the center has:

(A) Obtained and maintained a satisfactory record of federal manufacturing facility inspection

and licensure, where appropriate;

(B) obtained and maintained a satisfactory record of accreditation status from a nationally recognized accreditation organization utilizing internationally recognized standards of accreditation (such as the foundation for accreditation of cellular therapy) for center facilities producing clinical grade stem cells; and

(C) satisfied all other rules of governance and administration otherwise applicable to the type of activities to be conducted by the center at the university of Kansas medical center or the university of Kansas hospital authority.

(3) The center's commission to advance adult, cord blood and related stem cell and non-embryonic stem cell therapies for patient treatment and to do so in compliance with section 5, and amendments thereto, does not require the center to:

(A) Establish or operate a cell manufacturing facility at the university of Kansas medical center or the university of Kansas hospital authority; and

(B) supplant or exclude the participation of other appropriate cell manufacturing facilities engaged by the center that agree by appropriate lease and operating arrangements to comply with section 5, and amendments thereto.

(4) The center's commission to advance adult, cord blood and related stem cell and non-embryonic stem cell therapies for patient treatment and to do so in compliance with section 5, and amendments thereto, does not require the university of Kansas medical center or the university of Kansas hospital authority to participate in the operation of a cell manufacturing facility for the center.";

On page 2, in line 23, after "Fees" by inserting "may be"; in line 24, by striking ", clinical trial fees"; also in line 24, by striking "shall be paid"; by striking all in line 25; in line 26, by striking all before the period and inserting ". Fees, funds and grants may be received for conducting sponsored research and clinical trials. All such fees, funds and grants shall be paid, where appropriate, to the

university of Kansas medical center, the university of Kansas research institute, inc. or the university of Kansas endowment. The director, subject to the rules of governance and administration then otherwise applicable to the university of Kansas medical center and such other payees, may determine the appropriate payee";

Also on page 2, in line 36, after "fees" by inserting ", funds and grants"

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