

Institutional Review Board (IRB) Ad Hoc Committee Meeting Minutes March 1, 2018

The meeting was called to order at 9:45 a.m. by Chair J. Scott Holliday, D.O. Committee members present were: Frank Denton; Margaret McNeese, M.D.; Surendra Varma, M.D. and Timothy Webb, J.D. Julie Attebury and Jayaram Naidu, M.D. were absent. Other board members present were: Michael Cokinos; John R. Guerra, D.O.; Kandace B. Farmer, M.D.; Jeffrey L. Luna, M.D.; LuAnn Morgan; Karl W. Swann, M.D. and Sherif Zaafran, M.D. Board staff present were Scott Freshour, J.D., Interim Executive Director and General Counsel; Robert Bredt, M.D., Medical Director, and the Assistant General Counsels and various other staff.

Agenda item #2, Discussion, recommendation, and possible action regarding proposed rule amendments and rules review to 22 T.A.C.

Chapter 198 Standards for Use of Investigational Agents §198.1 Purpose §198.2 Definitions §198.3 Practice Guidelines for the Use of Investigational Agents §198.4 Use of Investigational Agents for Patients with Terminal Illnesses §198.5 Use of Investigational Stem Cell Treatments for Patients with Certain Severe Chronic Diseases of Terminal Illnesses.

Mr. Freshour gave a brief overview and history of stakeholder meetings. After discussion, Mr. Webb moved, Dr. Varma seconded, and the motion passed to approve the rule changes and rule review as presented for publication in the Texas Register for public comment.

There being no additional agenda items, Mr. Webb moved, Dr. Varma seconded, and the motion passed to adjourn at 9:56 a.m.