

Institutional Review Board (IRB) Ad Hoc Committee Meeting Minutes December 7, 2017

The meeting was called to order at 9:15 a.m. by J. Scott Holliday, D.O. Committee members present were Margaret McNeese, M.D. and Timothy Webb, J.D. Other board members present were: Julie Attebury; Michael Cokinos; Frank S. Denton; John R. Guerra, D.O.; Jeffrey L. Luna, M.D.; LuAnn Morgan; Jayaram B. Naidu, M.D.; Karl Swann M.D.; Surendra K. Varma, M.D. and Sherif Zaafran, M.D. Board staff present were Scott Freshour, J.D., Interim Executive Director; Robert Bredt, M.D., Medical Director, and the Assistant General Counsels Rob Blech, J.D.; Wendy Pajak, J.D.; Amy Swanholm, J.D. and Sarah Tuthill, J.D. 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.

After discussion, Dr. Varma, Dr. Naidu, Mr. Denton, and Ms. Attebury agreed to serve and were appointed as committee members.

Mr. Freshour reviewed the proposed rule amendments. Written comments were received and discussed. After discussion, the Committee directed staff to provide additional information and to provide a list of the current stakeholders.

There being no additional agenda items, Mr. Webb moved, Mr. Cokinos seconded, and the motion passed to adjourn at 9:38 a.m.