SUNRISE HEALTH
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INTRODUCTION

Sunrise Health and its IRB is committed to following the letter and spirit of the human subject protection regulations and guidance to ensure the integrity of the IRB decision-making process.

Federal research regulations set forth an IRB's authority to oversee human subjects research. Specifically, the mandate that an IRB "shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities" subject to the regulations [45 CFR 46.109(a)] [21 CFR 56.109(a)]. Further, the IRB "shall conduct continuing review of research" annually or more often when appropriate [45 CFR 46.109(e)] [21 CFR 56/109(f)]. The IRB also has the authority "to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects' [45 CFR 46.113] [21 CFR 56.113]. These regulations specify both the IRB's composition (inclusion of scientists, and at least one nonscientist and one unaffiliated member) and the criteria for IRB approval of research, among other requirements. In exercising this federal regulatory authority to review, approve, and provide continued oversight of research, the IRB communicates its decisions regarding research to investigators and to the institution through the Board of Trustees of Sunrise Health.

Importantly, the IRB must exercise independence as the entity authorized to oversee human subjects research. Federal regulations specify that if an IRB disapproves research, no one within an institution may overrule that decision and allow the research to go forward [45 CFR 46.112] [21 CFR 56.112]. Research that has IRB approval may, however, be subject to further institutional review, if appropriate. The independence of IRB decisions has taken on added importance given heightened attention to potential conflicts of interest that an institution or its investigators may have. Department of Health and Human Services (DHHS) guidance recommends that institutions consider several measures to protect research decisions from financial ones within an institution, including establishing measures to foster the IRB's independence.

Accordingly, all investigators who are either employees of Sunrise Health, or members of the Medical Staff of Sunrise Health are subject to the Sunrise Health Code of Conduct and Policies on Conflict of Interest. The Sunrise Health system for handling conflicts of interest is based on self-reporting. Self-reporting forms are sent to the investigators on an annual basis.

Voting members of the IRB are also required to disclose conflicts of interest and recuse themselves from participating in the discussion and vote on research activities with which they have a conflict of interest as defined in the Conflicts of Interest Policy for IRB Members. IRB members may, at the request of the IRB, provide information about the research prior to leaving the room for the discussion and the vote on the research.