Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 100	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	LATEST REVIEW/REVISION: 08/2020
POLICY: IRB Statement of Compliance	PAGE 1 OF 1	

FWA# FWA00001078 (Expiration June 5, 2024)

Consists of two Boards both registered in the Office for Human Research Protection (OHRP)

IRB #1Biomedical IRB# **IRB00000155** (Expiration July 1, 2022) Chair:
Mary Kunes-Connell, PhD

Applicable Regulations: (DHHS) regulation 45 CFR 46
(FDA) 21 CFR 11, 21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 812 and 21 CFR 814
(ICH) E6 The International Conference on Harmonisation (for Drugs and Biologicals)

IRB #2 Social Behavioral IRB# **IRB00007137** (Expiration July 1, 2022) Chair:
Amy Badura Brack, PhD

Applicable Regulations: (DHHS) regulation 45 CFR 46

Compliance Statement

The IRB is organized and operates under the applicable laws and regulations.

The IRB is duly constituted:

1. Has at least 5 members
2 . Has at least one member whose primary concerns are in scientific areas
3 . Has at least one member whose primary concerns are in nonscientific areas
3. Has at least one member who is independent of the institution

The IRB has written procedures for initial and continuing review (full and expedited) of clinical trials, prepares written minutes of convened meetings and retains records pertaining to the review and approval process.

Human Subject Research Protection Program at Creighton University has received full accreditation from AAHRPP on December 15, 2019. Human Subject Research Protection Program at Creighton University received initial full accreditation from AAHRPP on December 6, 2011.