



February 7, 2019

**RE: Emory University IRB  
FWA 00005792 (Expires October 15, 2023)  
IORG 0000267 (Expires November 09, 2021)**

To Whom It May Concern:

**Regulatory framework:** The Emory University IRB facilitates ethically responsible human subjects research by assuring the rights and welfare of study participants. Emory University complies with the federal regulations for the protection of human research subjects (45 CFR 46 Subparts A-D, 45 CFR 164.508-514, 21 CFR 50, 21 CFR 56, and applicable portions of 21 CFR 54, 21 CFR 312, 21 CFR 812, and 21 CFR 814).

Although the Emory University IRB has not officially adopted the ICH-GCP guidelines, its policies and procedures are in accordance with the ICH-GCP guidelines as published in the Federal Register, May 9, 1997 regarding Institutional Review Board/Independent Ethics Committee (IRB/IEC) criteria 3.1 through 3.4 of E-6.

**IRB Registration:**

Biomedical IRB Registration #569  
Sociobehavioral IRB Registration #453

Expires November 09, 2021  
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**IRB Membership Qualifications:**

**The Biomedical IRB** has seven (6) subcommittees (five that review protocols and one that reviews noncompliance matters and unanticipated problems). Each subcommittee is duly constituted with eleven (11) voting members and one prisoner representative who participates only in prisoner-related reviews.

**The Sociobehavioral IRB** is duly constituted with nine (8) voting members and one prisoner representative who participates only in prisoner-related reviews.

For both IRB's, quorum at each meeting of each committee requires the presence of an unaffiliated non-scientist ("community") member. In addition, conflicted members recuse themselves and leave the room for the discussion and vote.

Should you have any questions about this information, please email the Emory IRB at [irb@emory.edu](mailto:irb@emory.edu) and refer to this letter.

Thank you.

Regards,

*Rebecca Rousselle*

Rebecca Rousselle, BA, CIP

IRB Director