IRB Fees - Effective July 1, 2018

Institutional Review Board (IRB) fees are assessed for all industry sponsored research projects that meet the following NIH definition of a clinical trial: "A research study¹ in which one or more human subjects² are prospectively assigned³ to one or more interventions⁴ (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes⁵."

Research projects reviewed by the MCW IRB and supported by a biomedical industry sponsor (typically drug or medical device companies, but not limited to those industries) are subject to the IRB review fee. Fees are assessed for BOTH industry-sponsored and "investigator-initiated" for-profit funded projects.

When the MCW IRB defers IRB review responsibility for a research project supported by an industry sponsor to a different* single or central IRB, the study is subject to the Administrative oversight fee. Only the MCW IRB reliance specialist has the authority to permit deferral of MCW IRB review responsibility to a different single or central IRB.

The table below lists the pricing, which will go into effect for all new industry sponsored studies submitted on or after July 1, 2018:

Fee Name	Amount (7/1/18)
IRB Review	\$7000
Administrative Oversight ^a	\$3500
^a Reliance processing and oversight fee for projects deferred to an external IRB.	

The MCW IRB will assess a one-time, all-inclusive initial review fee. This fee should be included in the budget research at 45 CFR 46.102(d).

²See Common Rule definition of human subject at <u>45 CFR 46.102(f)</u>.

³The term "*prospectively assigned*" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

⁴An *intervention* is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more healthrelated biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

⁵*Health-related biomedical or behavioral outcome* is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or