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 study[1] in which one or more human subjects[2] are prospectively assigned[3] to one or more interventions[4] (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes[5]."

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 and negotiated with the funding agency. All other submission review for the lifetime of the project including continuing review reports, amendments and reportable events is provided by the IRB at no additional cost.

For questions regarding these new fees, contact the MCW IRB Office.

** Medical College of Wisconsin, Froedtert System facilities, Children's Hospital of Wisconsin, and BloodCenter of Wisconsin facilities including the Blood Research Institute are not considered "different" institutions for the purposes of this IRB billing policy.*

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[1]See Common Rule definition of *research* at 45 CFR 46.102(d).

[2]See Common Rule definition of *human subject* at 45 CFR 46.102(f).

[3]The 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.

[4]An *intervention* is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related 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 information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life."