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Medical College of Wisconsin Institutional Review Board Fees

Standard MCW IRB Review

The standard Institutional Review Board (IRB) fee is assessed for the review of any industry sponsored research project 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 an industry sponsor (typically drug or medical device companies, but not limited to those industries) are subject to this IRB fee. It is assessed for BOTH industry-sponsored and "investigator-initiated" for-profit funded projects.

This fee is for projects that do not include any external[6] relying sites. Separate fees may apply to studies involving relying sites as noted in the single IRB section below.

Fee Name	Amount
Standard IRB Review	$7000

The MCW IRB will invoice this one-time all-inclusive review fee after the initial IRB decision date. All other reviews during the lifetime of the project, including continuing review reports, amendments and reportable events are provided by the IRB at no additional cost. This fee is non-negotiable and should be included in the study budget.

For questions regarding this IRB fee, please contact the MCW IRB Office.

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

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

[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."

[6] External Site is defined as a location other than Medical College of Wisconsin, Froedtert System facility, Children's Wisconsin facility, Versiti facility (including Blood Research Institute)

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MCW serving as sIRB

Single IRB (sIRB) review occurs when research is being conducted at/by multiple engaged institutions but only one institution's IRB reviews and approves the research for all sites. Both NIH policy[7] and the Common Rule[8] from the Office of Human Research Protections have mandated sIRB review for most multi-site studies. Therefore, sIRB review is required for any project funded or supported by NIH or federal agencies that have adopted the Common Rule, and MCW will expect to be asked to serve as the sIRB when MCW is the primary awardee.

MCW sIRB service is assessed a fee regardless of the type of funding. To request a fee quote, submit the "Request for Single or Central IRB Services from MCW IRB" form[9] and a copy of the protocol/specific aims to the MCW Reliance Team. Cost of IRB related activities performed on behalf of other institutions is recoverable by MCW[10].

IMPORTANT: The fee structure below is a framework of how sIRB quotes are generated. You still must submit a reliance request an obtain an official quote from the MCW IRB Reliance Team prior to submission of a grant. The MCW IRB office will only honor quotes generated by our office. If you do not obtain this documentation, there is a chance that MCW may not be able to serve as sIRB for your project. The addition of new sites may require a revised quotation.

NIH and other Federally Funded Projects	
There are three layers (a-c) totaling into a single charge that covers a full five-year grant period (one year of no-cost extension to that grant is permissible):	
a. Base fee for every single/central IRB project	$2,000
b. Complexity surcharge (determined by the MCW Human Research Protections Program)	
• High (first in human, Phase I, interventional)	add $4,000
• Medium (Phase II/III, high-risk drug/device)	add $2,000
• Low (minimal risk procedures)	add $0
c. Per external[11] site	add $2,000/site

[7] See NIH policy titled 'Single IRB for Multi-Site or Cooperative Research'.
[8] See Common Rule description of Cooperative Research at 45 CFR 46.114.
[9] The 'Request for Single or Central IRB Services from MCW IRB' form can be found on the MCW HRPP Website.
[10] NIH policy: Scenarios to Illustrate the Use of Direct and Indirect Costs for Single IRB Review under the NIH Policy on the Use of a Single IRB for Multi-site Research NOT-OD-16-109.
[11] "External site" is defined as a study site other than Medical College of Wisconsin, Froedtert System facility, Children's Wisconsin facility, Versiti facility (including Blood Research Institute), that is engaged in human subjects research as a part of this project.

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Other Funding Sources (i.e. for profit funding, no funding, not-for-profit funding)	
There are four layers (a-d) totaling into a single charge that covers five-years – projects that last longer will require an additional fee:	
a. Base protocol review fee	$5,000
b. Base multi-sight network oversight fee	$7,000
c. Complexity surcharge (determined by the MCW HRPP)	
• High (first in human, Phase I, interventional)	add $6,000
• Medium (Phase II/III, high-risk drug/device)	add $4,000
• Low (minimal risk procedures)	add $0
d. Per external[12] site	add $2,000/site

The MCW IRB will invoice the sIRB fee after the initial IRB decision date or date that first relying site is added, as applicable. Invoices will include the total fee unless a payment plan is requested and agreed upon by the MCW IRB office. In that case, the fee may be invoiced over the life of the grant.

All reviews including continuing review reports, amendments and reportable events are included in this fee. This sIRB fee should be included in the budget and negotiated with the funding agency. For NIH grants, sIRB fees should be charged to the grant as outlined in NIH Grant Policy[13].

Non-MCW IRB Review – Reliance on an External IRB

When MCW relies on a non-MCW IRB for review of a research project supported by an industry sponsor, the study is subject to the Administrative Oversight fee for the work we are required to perform. This is a one-time fee that covers reliance processing and oversight. Only the MCW Reliance Team has the authority to permit deferral of IRB review responsibility to a non-MCW IRB, and this process is documented via the reliance request pathway in eBridge.

Fee Name	Amount
Administrative Oversight	$3500

The MCW IRB Reliance team will invoice this fee after the IRB approval date or final reliance processed date, as applicable. For questions regarding this IRB fee, please contact the MCW Reliance Team.

[12] "External site" is defined as a study site other than Medical College of Wisconsin, Froedtert System facility, Children's Wisconsin facility, Versiti facility (including Blood Research Institute), that is engaged in human subjects research as a part of this project.
[13] NIH policy: Scenarios to Illustrate the Use of Direct and Indirect Costs for Single IRB Review under the NIH Policy on the Use of a Single IRB for Multi-site Research NOT-OD-16-109

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Fee Justification

All MCW IRB fees cover services provided by the MCW Human Research Protection Program to facilitate efficient management and compliant regulatory review of research projects. The following list includes a brief description of these services that may apply depending on fee and study type.

- Routing for local context considerations and resource allocation
- Routing for Safety Committee reviews
- Pre-review and completeness check of initial study submission application
- Review of all consent and assent forms for accuracy and policy adherence
- Review of petitions to alter MCW consent and assent form template language
- Negotiation of reliance agreements
- Review of local context for relying sites
- Review by IRB committee or Reliance Team for regulatory compliance and HIPAA determinations
- Review by IRB committee or Reliance Team for appropriate human research protections
- Review of continuing progress reports, amendments, reportable events, and safety documents for the life of the project
- Institutional support for privacy and confidentiality issues for participants
- Maintenance of Research Subject Advocate contact and associated liaison services for participants in event participant is not comfortable communicating with Principal Investigator or study team
- Human Subject Research Protection and Good Clinical Practice training for all research staff
- Training opportunities to assure competency and currency in regulations related to human subject research
- Oversight and guidance for clinical research activities conducted across MCW and affiliate facilities
- Maintenance of IRB committee operations
- Maintenance of MCW Consent Form Templates that follow MCW policy as well as regulatory requirements

Please note that IRB Fees do not cover the effort and resources required by investigators and study teams to prepare, negotiate, submit, or execute any documents or processes required for clinical research project initiation, maintenance, or closure.