University of Wisconsin
SCHOOL OF MEDICINE AND PUBLIC HEALTH

Marc K. Drezner, M.D.
Senior Associate Dean for Clinical and Translational Research
Executive Director, Institute for Clinical and Translational Research
Professor of Medicine

MEMORANDUM

Date: August 7, 2015

To: School of Medicine & Public Health Department Chairs

From: Marc K. Drezner, MD MD.
Senior Associate Dean for Clinical & Translational Research

Re: Clarifications to Health Sciences Institutional Review Boards (IRBs) Fees

The purpose of this memorandum is to replace the IRB fee schedule issued on July 1, 2008 pursuant to studies reviewed by a UW Health Sciences IRB. Changes in fee structure for the use of a commercial IRB are available in a separate memorandum dated August 7, 2015. The following changes and clarifications will be in effect as of September 1, 2015:

1) With the decoupling of commercial from the UW IRB fees, the UW Health Sciences IRB fee for review of changes in principal investigator will be reduced.
2) Clarifications are provided regarding definition of terms:
    a. A trainee project is defined as a research study primarily conducted by a resident or fellow, as part of their program requirements and would not exist or continue without the trainee's involvement.
    b. IRB review fees will be not charged for studies wherein 1) greater than 50% of the funding is provided by federal or other non-industry sources and 2) indirect costs from these sources are 10% or greater.

The updated UW Health Sciences IRB Fee Schedule is attached as Appendix A. The former fee schedule is available at https://kb.wisc.edu/images/group78/shared/HSIRBsFeePolicy7-1-2008.pdf.

If you have any questions, feel free to contact me.

4246 Health Sciences Learning Center
750 Highland Avenue Madison, Wisconsin 53705
Phone: 608-262-9288 Fax: 608-265-2158

Appendix A

UW-Madison IRB Fee Schedule for Health Sciences IRBs and Western IRB Reviews

Table 1 below shows the IRB fees for new studies submitted to a UW Health Sciences IRB for review after September 1, 2015. With the exceptions described below, these fees apply to a) personnel conducting human subjects research under their School of Medicine & Public Health (SMPH) appointments and b) studies supported by industry funding regardless of whether the research is conducted under an SMPH appointment. **Table 2** reflects the new fee schedule for studies reviewed by Western IRB.

Table 1. Fees for UW Health Sciences IRBs Review

Type of Submission	**Fee Schedule Effective as of September 1, 2015**	
	Trainee Project[1]	Other Projects
Initial Review	$1172	$2344
Five-Year Replacement Initial Review	$586	$1172
Continuing Review	$567	$1134
Change of Protocol, including changes in Principal Investigators	$157	$313

Exceptions to UW Health Sciences IRB fee schedule

IRB fees will not be applied to the following:

- Human subjects research that qualifies for exemption.
- Human subjects research wherein 1) greater than 50% of the funding is provided by federal or other non-industry sources and 2) indirect costs from these sources are 10% or greater.
- Research studies supported by funding from the Wisconsin Partnership Program or the Institute for Clinical & Translational Research (ICTR). The funding must not be limited support (e.g., funds for equipment or laboratory analyses).
- Medical records research that is not industry funded.
- Applications for projects that do not meet the definition of human subjects research (e.g., quality improvement projects).
- Applications involving the non-research use of a Humanitarian Use Device.
- Applications for an emergency or one-time use of an investigational drug, biologic, or device.
- Research studies that primarily involve research activities that are conducted in fulfillment of a University of Wisconsin-Madison degree and would not exist or continue without the student's involvement. Note: If a project is designated as both a student and a trainee project, the trainee rate will apply if the study otherwise qualifies for an IRB review fee.

[1]A trainee project is defined as research study primarily conducted by a resident or fellow as part of their program requirements and would not exist or continue without the trainee's involvement.

Study teams will be invoiced for industry-sponsored studies reviewed by a UW Health Sciences IRB when industry support is not limited to the provision of a drug or device. Submissions for all other studies reviewed by a UW Health Sciences IRB, including those with partial industry support (e.g., drug or device provided but no further funding from industry), will be tracked by the Health Sciences IRBs office. Departments will be provided with a summary of the fees they have incurred near the end of the fiscal year. Each department is given an option to identify specific funding for each project or have the charges applied to upcoming SMPH MAMA fund allocation.

Table 2. Fees for Western IRB review

Type of Submission	**Combined Fees for WIRB Reviews Effective as of September 1, 2015**		
	WIRB fee	**PLUS**	UW Institutional Compliance Review Fee
Initial Review	Per WIRB fee schedule	**PLUS**	$1500
Continuing Review	Per WIRB fee schedule	**PLUS**	$0
Change of Protocol, including changes in Principal Investigators	Per WIRB fee schedule	**PLUS**	$0
Other WIRB reviews and services	Per WIRB fee schedule	**PLUS**	$0

See also the July 27, 2015 memorandum regarding charges for fully industry-sponsored studies reviewed by Western IRB.