

Investigator Guidance Series

University of Utah Institutional Review Board

FEES TO REVIEW FOR-PROFIT, SPONSORED HUMAN SUBJECT RESEARCH

PLEASE NOTICE – The following fee information does not take effect until July 1, 2008.

As of July 1, 2008, the IRB will increase the fees charged to review for-profit sponsored research. This is the first increase since the fees were instituted in 2004 and is due in large part to the increase in F&A to 32.7%. IRB fees support a number of Research Administration operations including the ERICA system. Existing studies and studies that are submitted on or after July 1, 2008, will be subject to the new fee schedule. There will be no “grandfather clause” as this will only create confusion and additional administrative burden for researchers and the IRB. The current Fee Schedule will remain in effect until July 1, 2008. The new fees will be as follows:

New Study Application

Check:	\$1600
Campus Order:	\$1206
F&A:	\$394

Continuing Review

Check:	\$575
Campus Order:	\$434
F&A:	\$141

Sponsored Initiated Studies

Check:	\$575
Campus Order:	\$434
F&A:	\$141

Continuing Review & Amendment

Check:	\$1150
Campus Order:	\$867
F&A:	\$283

Please remember that these fees do not take effect until July 1, 2008. The fees will remain as indicated below until July 1.

September 7, 2004 – The IRB initiated charges for all new, for-profit/industry sponsored studies. These fees will only apply to new studies submitted on or after September 7, 2004, and all currently approved projects will be grandfathered. Again, any studies submitted before September 7, 2004, will not be subject to fees. Studies that are investigator-initiated, federally-funded grants, and non-profit grants will not be subject to these fees.

Type of Application

IRB Fee

IRB Fee

(If paid by Campus Order)

New Study Application

\$1,500

\$1,177.00

+ \$ 384.87 (F&A)

\$1,561.87

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

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Sponsor-Initiated Amendment (EACH)	\$500		\$392.00
		+	\$128.18 (F&A)

			\$520.18
Renewal/Continuing Review	\$500		\$392.00
		+	\$128.18 (F&A)

			\$520.18
Administrative Closures*	\$500		\$392.00
		+	\$128.18 (F&A)

			\$520.18

Frequently-Asked Questions

Q: Will for-profit sponsored research submitted before September 7, 2004, be subject to IRB fees for renewals, amendments, and administrative closure?

A:	No. All for-profit sponsored research submitted before September 7, 2004, will be grandfathered. IRB fees will not be charged for actions such as renewals, amendments, and administrative closures.
Q:	Will there be a charge for Adverse Event Reports and/or Protocol Deviations?
A:	No. There will be no charge for Adverse Event Reports and/or Protocol Deviations.
Q:	When is the fee due?
A:	The fee is due when the project is submitted to the IRB. The review process will not begin until fees are paid. To accomplish this, the Document Summary Sheet and Prelim Project request should be sent to OSP approximately 1 week before the IRB application is submitted, to allow time for a project number to be created by Research Accounting.
Q:	As part of the process for beginning a clinical trial, it is common to submit the protocol for IRB approval while the contract is still in negotiation. Sometimes the contract is never signed and the study does not take place. Will the IRB fee still be charged if the contract is not signed, and the study is never conducted at the University of Utah?
A:	The IRB Fee is charged as a result of the time, effort, and resources used in conducting a review. The fee applies regardless of whether a project begins.
Q:	What will be done with the revenue generated by these fees?
A:	The revenue generated by these fees will be used to enhance Research Integrity and IRB services, implement and maintain a web-based (paperless) submission process, add new staff, fund an AAHRPP audit/certification, and improve training efforts for research compliance activities across campus.

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	Q: Will for-profit research receive special consideration or be expedited because there is a fee associated with the review?
	A: No. All research submitted to the IRB will be processed and reviewed in the same manner regardless of fees. IRB Reviewers are not compensated, and all revenue generated by fees will be used to enhance the service we provide.
	Q: How do I budget for these new fees?
	A: The Document Summary Sheet and Prelim Project request should be sent to OSP approximately one week before the IRB application is submitted to allow time for a project number to be created by Research Accounting. After the preliminary project is created, a campus order must be submitted to the IRB along with the application. The IRB will charge the prelim project (these costs would later be reimbursed by the sponsor upon execution of the contract).
	*An <i>Administrative Closure</i> is when the IRB must close a study for failing to renew.

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